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WHEN: Tuesday, March 12, 2013
9 a.m.–12:30 p.m.

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW.
Washington, DC 20002

RESERVATIONS: (202) 741–6008

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 966

[Doc. No. AMS–FV–12–0051; FV12–966–1 IR]

Tomatoes Grown in Florida; Decreased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim rule with request for comments.

SUMMARY: This rule decreases the assessment rate established for the Florida Tomato Committee (Committee) for the 2012–13 and subsequent fiscal periods from $0.037 to $0.024 per 25-pound carton of tomatoes handled. The Committee locally administers the marketing order which regulates the handling of tomatoes grown in Florida. Assessments upon Florida tomato handlers are used by the Committee to fund reasonable and necessary expenses of the program. The fiscal period begins August 1 and ends July 31. The assessment rate will remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Effective February 11, 2013. Comments received by April 9, 2013, will be considered prior to issuance of a final rule.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Fruit and Vegetable Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or Internet: *http://www.regulations.gov.* Comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http://www.regulations.gov.* All comments submitted in response to this rule will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the Internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Corey Elliott, Marketing Specialist or Christian D. Nissen, Regional Director, Southeast Marketing Field Office, Marketing Order and Agreement Division, Fruit and Vegetable Program, AMS, USDA; Telephone: (863) 324–3375, Fax: (863) 325–8793, or Email: *Corey.Elliott@ams.usda.gov* or *Christian.Nissen@ams.usda.gov.*

Small businesses may request information on complying with this regulation by contacting Laurel May, Marketing Order and Agreement Division, Fruit and Vegetable Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Laurel.May@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement No. 125 and Order No. 966, both as amended (7 CFR part 966), regulating the handling of tomatoes grown in Florida, hereinafter referred to as the ''order.'' The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Order 12866.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the marketing order now in effect, Florida tomato handlers are subject to assessments. Funds to administer the order are derived from such assessments. It is intended that the assessment rate as issued herein will be applicable to all assessable Florida tomatoes beginning August 1, 2012, and continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This rule decreases the assessment rate established for the Committee for the 2012–13 and subsequent fiscal periods from $0.037 per 25-pound carton to $0.024 per 25-pound carton of Florida tomatoes.

The Florida tomato marketing order provides authority for the Committee, with the approval of USDA, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members of the Committee are producers of Florida tomatoes. They are familiar with the Committee's needs and with the costs for goods and services in their local area and are thus in a position to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

For the 2011–12 and subsequent fiscal periods, the Committee recommended, and USDA approved, an assessment rate that would continue in effect from fiscal period to fiscal period unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other information available to USDA.

The Committee met on August 22, 2012, and unanimously recommended 2012–13 expenditures of $1,672,952 and an assessment rate of $0.024 per 25-pound carton of tomatoes. In comparison, last year's budgeted expenditures were $1,561,952. The assessment rate of $0.024 is $0.013 lower than the rate currently in effect. The Committee recommended decreasing the assessment rate by using additional funds from reserves to help reduce overall industry costs.

The major expenditures recommended by the Committee for the 2012–13 year include $750,000 for education and promotion, $436,372 for salaries, $250,000 for research, $66,000 for office rent, and $48,000 for employee health insurance. Budgeted expenses for these items in 2011–12 were $640,500, $436,372, $250,000, $64,000 and $48,000, respectively.

The assessment rate recommended by the Committee was derived by reviewing anticipated expenses, shipments, funds from block grants, interest income, and available reserves. Florida tomato shipments for the year are estimated at 35 million 25-pound cartons which should provide $840,000 in assessment income. Income derived from handler assessments, along with funds from the Committee's authorized reserve, interest income, and funds from block grants, will be adequate to cover budgeted expenses. Funds in the reserve (currently $729,000) will be kept within the maximum permitted by the order of not to exceed one fiscal period's expenses as authorized in § 966.44.

The assessment rate established in this rule will continue in effect indefinitely unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other available information.

Although this assessment rate is effective for an indefinite period, the Committee will continue to meet prior to or during each fiscal period to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of Committee meetings are available from the Committee or USDA. Committee meetings are open to the public and interested persons may express their views at these meetings. USDA will evaluate Committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking will be undertaken as necessary. The Committee's 2012–13 budget and those for subsequent fiscal periods will be reviewed and, as appropriate, approved by USDA.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 80 handlers of tomatoes in the production area and approximately 100 producers subject to regulation under the marketing order. Small agricultural service firms are defined by the Small Business Administration (SBA) as those whose annual receipts are less than $7,000,000 and small agricultural producers are defined as those having annual receipts less than $750,000 (13 CFR 121.201).

Based on industry and Committee data, the average annual price for fresh Florida tomatoes during the 2011–12 season was approximately $6.62 per 25-pound container, and total fresh shipments for the 2011–12 season were approximately 38,175,363 25-pound cartons of tomatoes. Committee data indicates that approximately 21 percent of the handlers handle 90 percent of the total volume shipped. Based on the average price, about 80 percent of handlers could be considered small businesses under SBA's definition. In addition, based on production data, grower prices as reported by the National Agricultural Statistics Service, and the total number of Florida tomato growers, the average annual grower revenue is below $750,000. Thus, the majority of handlers and producers of Florida tomatoes may be classified as small entities.

This rule decreases the assessment rate established for the Committee and collected from handlers for the 2012–13 and subsequent fiscal periods from $0.037 to $0.024 per 25-pound carton of tomatoes. The Committee unanimously recommended 2012–13 expenditures of $1,672,952 and an assessment rate of $0.024 per 25-pound carton of tomatoes. The assessment rate of $0.024 is $0.013 lower than the 2011–12 rate. The Committee recommended decreasing the assessment rate by using additional funds from reserves to help reduce overall industry costs. The quantity of assessable tomatoes for the 2012–13 season is estimated at 35 million cartons. Thus, the $0.024 rate should provide $840,000, in assessment income. Income derived from handler assessments, along with funds from the Committee's authorized reserve, interest income, and funds from block grants, will be adequate to cover budgeted expenses.

The major expenditures recommended by the Committee for the 2012–13 year include $750,000 for education and promotion, $436,372 for salaries, $250,000 for research, $66,000 for office rent, and $48,000 for employee health insurance. Budgeted expenses for these items in 2011–12 were $640,500, $436,372, $250,000, $64,000 and $48,000, respectively.

The Committee reviewed and unanimously recommended 2012–13 expenditures of $1,672,952. Prior to arriving at this budget, the Committee considered information from various sources, such as the Committee's Executive Subcommittee, Finance Subcommittee, and Education and Promotion Subcommittee. Alternative expenditure levels were discussed by these groups. The assessment rate recommended by the Committee was derived by reviewing anticipated expenses and shipments of Florida tomatoes, expected funds from block grants, interest income, and available reserves. Florida tomato shipments for the year are estimated at 35 million 25-pound cartons which should provide $840,000 in assessment income. Assessments, along with funds from block grants and interest income, will be approximately $42,952 less than the anticipated expenses, which the Committee determined to be acceptable. Funds from the Committee's financial reserve will be used to make up the shortfall in revenue.

A review of historical information and preliminary information pertaining to the upcoming crop year indicates that the grower price for the 2012–13 season could range between $3.68 and $12.09 per 25-pound carton of tomatoes. Therefore, the estimated assessment revenue for the 2012–13 crop year as a percentage of total grower revenue could range between .2 and .7 percent.

This action decreases the assessment obligation imposed on handlers. Assessments are applied uniformly on all handlers, and some of the costs may be passed on to producers. However, decreasing the assessment rate reduces the burden on handlers, and may reduce the burden on producers. In addition, the Committee's meeting was widely publicized throughout the Florida tomato industry and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the August 22, 2012, meeting was a public meeting and all entities, both large and small, were able to express views on this issue. Finally, interested persons are invited to submit comments on this interim rule, including the regulatory and

informational impacts of this action on small businesses.

In accordance with the Paperwork Reduction Act of 1995, (44 U.S.C. chapter 35), the order's information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0178 Vegetable and Specialty Crops. No changes in those requirements as a result of this action are necessary. Should any changes become necessary, they would be submitted to OMB for approval.

This action imposes no additional reporting or recordkeeping requirements on either small or large Florida tomato handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *www.ams.usda.gov/MarketingOrdersSmallBusinessGuide.* Any questions about the compliance guide should be sent to Laurel May at the previously-mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendation submitted by the Committee and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect, and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) The 2012–13 fiscal period began on August 1, 2012, and the marketing order requires that the rate of assessment for each fiscal period apply to all assessable Florida tomatoes handled during such fiscal period; (2) this action decreases the assessment rate for assessable Florida tomatoes beginning with the 2012–13 fiscal period; (3) handlers are aware of this action which was unanimously recommended by the Committee at a public meeting and is similar to other assessment rate actions issued in past years; and (4) this interim rule provides a 60-day comment period, and all comments timely received will be considered prior to finalization of this rule.

List of Subjects in 7 CFR Part 966

Marketing agreements, Reporting and recordkeeping requirements, Tomatoes.

For the reasons set forth in the preamble, 7 CFR part 966 is amended as follows:

PART 966—TOMATOES GROWN IN FLORIDA

■ 1. The authority citation for 7 CFR part 966 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 966.234 is revised to read as follows:

§ 966.234 Assessment rate.

On and after August 1, 2012, an assessment rate of $0.024 per 25-pound carton is established for Florida tomatoes.

Dated: February 4, 2013.

David R. Shipman,

Administrator, Agricultural Marketing Service.

[FR Doc. 2013–02816 Filed 2–7–13; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0746; Directorate Identifier 2008–SW–035–AD; Amendment 39–17337; AD 2013–03–03]

RIN 2120–AA64

Airworthiness Directives; MD Helicopters, Inc., Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for MD Helicopters, Inc. (MDHI) Model 500N, 600N and MD900 helicopters to require determining the cure date for each NOTAR fan blade tension-torsion strap (T–T strap), establishing a calendar-time retirement life for certain T–T straps, reducing the retirement life of certain T–T straps, marking each T–T strap with the expiration date, creating a component record card for each T–T strap, and revising the airworthiness limitations section of the maintenance manual to reflect the changes to the retirement life. This AD was prompted by a report from the T–T strap manufacturer that, over a period of time, moisture may reduce the strength of a T–T strap. The actions are intended to prevent failure of a T–T strap, loss of directional control and subsequent loss of control of the helicopter.

DATES: This AD is effective March 15, 2013.

ADDRESSES: For service information identified in this AD, contact MD Helicopters, Inc., Attn: Customer Support Division, 4555 E. McDowell Rd., Mail Stop M615, Mesa, Arizona 85215–9734, telephone 1–800–388–3378, fax 480–346–6813, or on the web at *http://www.mdhelicopters.com.* You may review a copy of the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth Texas 76137.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, any incorporated-by-reference service information, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations Office, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: John Cecil, Aviation Safety Engineer, Los Angeles Aircraft Certification Office, Transport Airplane Directorate, FAA, 3960 Paramount Blvd., Lakewood, California 90712; telephone (562) 627–5228; email *john.cecil@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

On July 19, 2012, at 77 FR 42459, the **Federal Register** published our notice of proposed rulemaking (NPRM), which proposed to amend 14 CFR part 39 to include an AD that would apply to MDHI Model 500N and 600N helicopters with a NOTAR fan blade T–T strap part number (P/N) 500N5311–5 and MDHI Model MD900 helicopters with a T–T strap, P/N 500N5311–5, P/N 900R3442009–101, P/N 900R3442009–103, or P/N

900R6442009–103. That NPRM proposed to require determining the cure date for each T–T strap, establishing a calendar-time retirement life for certain T–T straps, reducing the retirement life of certain T–T straps, marking each T–T strap with the expiration date, creating a component record card for each T–T strap, and revising the airworthiness limitations section of the maintenance manual to reflect the changes to the retirement life. This AD was prompted by information from the T–T strap manufacturer indicating that, over time, the T–T straps can absorb moisture, which can weaken the T–T strap and cause it to fail. The proposed requirements were intended to prevent failure of a T–T strap, loss of directional control and subsequent loss of control of the helicopter.

Comments

We gave the public the opportunity to participate in developing this AD, but we received no comments on the NPRM (77 FR 42459, July 19, 2012).

FAA's Determination

We have reviewed the relevant information and determined that an unsafe condition exists and is likely to exist or develop on other products of these same type designs and that air safety and the public interest require adopting the AD requirements as proposed.

Related Service Information

We have reviewed one MDHI service bulletin, which contains two service bulletin numbers, SB500N–029R3, applicable to MDHI Model 500N helicopters; and SB600N–046R3, applicable to MDHI Model 600N helicopters, dated July 9, 2008. We have also reviewed MDHI SB900–107R1, dated March 14, 2008, applicable to MDHI Model MD900 helicopters. The service bulletins describe procedures for establishing a retirement life for each affected T–T strap by determining the manufacturer's cure date and marking the T–T strap with an expiration date; creating a component record card for each affected T–T strap; replacing T–T straps that have been in service beyond their revised life limit; and recording compliance with the service information in the Rotorcraft Log Book.

Differences Between This AD and the Service Information

This AD differs from the previously described service bulletins as follows:

- This AD contains requirements for T–T straps that are installed or will be installed on the affected helicopters, but does not address a part that is in storage.
- For a T–T strap with five or more calendar years from the manufacturer's cure date, this AD requires, before further flight, replacing the T–T strap with an airworthy T–T strap. The service bulletins specify the T–T strap to be replaced within six, 12, or 24 months, depending on the manufacturing cure date.
- The service bulletins specify sending removed parts to the manufacturer. This AD does not require such action.
- This AD requires reducing the life limit for any T–T strap, P/N 500N5311–5, to 2500 hours TIS if the T–T strap has been installed on a MDHI Model MD900 helicopter.

Costs of Compliance

We estimate that this AD will affect 111 helicopters of U.S. Registry, including 73 helicopters in the combined MDHI Model 500N and MDHI Model 600N fleet, and 38 MDHI Model MD900 helicopters. Determining the manufacturer's cure date, the expiration date, marking an expiration date on the T–T strap, creating the component record card, revising the applicable airworthiness limitations section of the maintenance manual, and re-installing the T–T strap will take about 40 work-hours per helicopter for Model 500N and Model 600N helicopters, and 32 work-hours per helicopter for Model MD900 helicopters, at an average labor rate of $85 per work-hour. Required parts will cost about $1,340 per T–T strap. Based on these figures, the total cost impact of the AD on U.S. operators will be about $543,180 for the entire fleet, assuming all T–T straps will be marked, and assuming 11 helicopters will need T–T straps replaced (13 T–T straps per helicopter).

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866;

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2013–03–03 MD Helicopters, Inc. (MDHI): Amendment 39–17337; Docket No. FAA–2012–0746; Directorate Identifier 2008–SW–035–AD.

(a) Applicability

MDHI Model 500N and 600N helicopters, with a NOTAR fan blade tension-torsion strap (T–T strap), part number (P/N) 500N5311–5; and MDHI Model MD900 helicopters, with a T–T strap, P/N 500N5311–5, P/N 900R3442009–101, P/N 900R3442009–103, or P/N 900R6442009–103; certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as a decrease, over time, in the strength of a T–T strap caused by moisture. This condition could result in failure of a T–T strap, loss of directional control, and subsequent loss of control of the helicopter.

(c) Effective Date

This AD becomes effective March 15, 2013.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

(1) Within six months, determine the manufacturer's cure date of each of the 13 T–T straps.

(i) For a T–T strap with five or more calendar years from the manufacturer's cure date, before further flight, replace the T–T strap with an airworthy T–T strap.

(ii) For a T–T strap with less than five calendar years from the manufacturer's cure date, mark the expiration date on the T–T strap face in permanent ink.

(2) Thereafter, before installing a T–T strap, mark the expiration date on the T–T strap using permanent ink. The expiration date is five years from the date the T–T strap package was opened, or if that date was not recorded, five years from the manufacturer's cure date.

(3) On or before the date you comply with paragraph (e)(1) or (e)(2) of this AD, create a component record card for each T–T strap and record on the card the manufacturer's cure date or the date that the T–T strap package was opened, if that date was recorded previously, and the T–T strap expiration date.

(4) Revise the Airworthiness Limitations section of the maintenance manual by establishing:

(i) A calendar life limit for the T–T straps, P/N 500N5311–5, 900R3442009–101, 900R3442009–103, and 900R6442009–103 of five years from the date the T–T strap package was opened, or if that date was not recorded, five years from the manufacturer's cure date.

(ii) A 2,500 hour time-in-service (TIS) life limit for any T–T straps, P/N 500N5311–5, installed on a Model 500N or Model 600N helicopter that was previously installed on a Model MD900 helicopter.

Note to paragraph (e) of this AD: For the MDHI Model MD900 helicopters, AD 2006–18–01 (71 FR 51095, August 29, 2006) contains additional TIS life limits for T–T straps, P/N 900R3442009–103 and P/N 900R6442009–103 and additional inspection requirements for all four affected T–T straps, P/N 500N5311–5, P/N 900R3442009–101, P/N 900R3442009–103, and P/N 900R6442009–103.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles Aircraft Certification Office, FAA, may approve AMOCs for this AD. Send your proposal to: John Cecil, Aviation Safety Engineer, Los Angeles Aircraft Certification Office, Transport Airplane Directorate, FAA, 3960 Paramount Blvd., Lakewood, California 90712; telephone (562) 627–5228; email *john.cecil@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(g) Additional Information

MDHI has issued one service bulletin with two numbers, SB500N–029R3 for the Model 500N helicopters, and SB600N–046R3 for the Model 600N helicopters, dated July 9, 2008. MDHI has also issued SB900–107R1, dated March 14, 2008, for the Model MD900 helicopters. These service bulletins, which are not incorporated by reference, contain information related to the subject of this AD. For service information identified in this AD, contact MD Helicopters, Inc., Attn: Customer Support Division, 4555 E. McDowell Rd., Mail Stop M615, Mesa, Arizona 85215–9734, telephone 1–800–388–3378, fax 480–346–6813, or on the web at *http://www.mdhelicopters.com.* You may review a copy of this service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 6410, Tail rotor blades.

Issued in Fort Worth, Texas, on January 29, 2013.

Lance T. Gant,

Acting Directorate Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2013–02582 Filed 2–7–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, and 1926

[Docket No. OSHA–H022K–2006–0062 (formerly Docket No. H022K)]

RIN 1218–AC20

Hazard Communication; Corrections and Technical Amendment

AGENCY: Occupational Safety and Health Administration (OSHA), DOL.

ACTION: Final rule: correction and technical amendment.

SUMMARY: OSHA is correcting its regulations that were amended by the Hazard Communication Standard final rule, published in the **Federal Register** on March 26, 2012. The majority of the corrections are to references inadvertently missed in the original publication of the final rule. Other corrections include correcting values or notations in tables, and updating references to terms.

DATES: Effective: February 8, 2013.

FOR FURTHER INFORMATION CONTACT:

Press inquiries: Frank Meilinger, Director, Office of Communications, OSHA, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1999.

General and technical information: Dorothy Dougherty, Director, Directorate of Standards and Guidance, OSHA, Room N–3718, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1950.

SUPPLEMENTARY INFORMATION:

I. Background

This notice corrects certain minor errors in the revisions to OSHA's Hazard Communication Standard, published at 77 FR 17574. The majority of these corrections change references in other OSHA standards made to ''material safety data sheet'' or ''MSDS'' to ''safety data sheet'' or ''SDS,'' which OSHA inadvertently missed in its original publication of the final rule. Other corrections include correcting values or notations in tables, and updating references to terms defined in the Hazard Communication Standard Final Rule, published on March 26, 2012.

Correction of Publication

The following corrections are made to the preamble to the final rule for the Hazard Communication Standard, published in the **Federal Register** on March 26, 2012 (77 FR 17574).

1. In the Preamble, on p. 17686, in the third column, the seventh paragraph *Estimated Total Burden Hours:* 11.3 million hours is revised to read *Estimated Total Burden Hours:* 10,689,248 hours.

2. In the Preamble, on p. 17755, in the third column, in the first paragraph the name ''David Levine'' is corrected to read ''Daniel Levine''.

3. In the Preamble, on p. 17712, Table XIII–1, the ''>20%'' value for Specific target organ toxicity Category 3 is corrected to read ''≥20%'' (both columns).

4. In the Preamble, on p. 17751, Table XIII–5, Health Effects Column for Standard No. 1910.1051. ''Cancer; eye and respiratory tract irritation; center nervous system effects; and flammability'' is corrected to read

''Cancer; eye and respiratory tract irritation; central nervous system effects; and flammability.''

The following table contains a summary of the codified changes made to the Hazard Communication final rule as it appeared at 77 FR 17574 and is provided for the regulated community. The changes are listed by the **Federal Register** page number on which they can be found, the standard being corrected, and a summary of the correction being made.

Page No.	Standard	Correction
Page 17776, third column	§ 1910.119, paragraph (d)(1) and Appendix C.	''material safety data sheet'' and the acronym ''MSDS'' are corrected to ''safety data sheet'' and ''SDS'', respectively.
On p. 17776, third column ...	§ 1910.120, paragraph (g), Appendices A and E.	''material safety data sheet'' and the acronym ''MSDS'' are corrected to ''safety data sheet'' and ''SDS'', respectively.
On p. 17778, first column	§ 1910.1001, Appendix J	''material safety data sheet'' and the acronym ''MSDS'' are corrected to ''safety data sheet'' and ''SDS'', respectively.
On p. 17782, third column ...	§ 1910.1044, Appendix B ...	Reference to ''Class IIIA combustible liquid'' is corrected to ''Category 4 flammable liquid''.
On p. 17784, first column	§ 1910.1048, Appendix A ...	The flammability class reference in Appendix A is updated to align with the § 1910.1200.
On p. 17785, second column, second paragraph.	§ 1910.1051 (l)(1)(ii)	''center nervous system effects'' is corrected to ''central nervous system effects''.
On p. 17785, second column	§ 1910.1052, Appendix A ...	The example label language in Appendix A is removed and the Appendix is corrected to reference classification and label requirements provided in § 1910.1200. ''material safety data sheet'' and the acronym ''MSDS'' are corrected to ''safety data sheet'' and ''SDS''.
On p. 17786	§ 1910.1200, Appendix E ...	Remove the entire Appendix E entitled, ''Appendix E to § 1910.1200—(Advisory)—Guidelines for Employer Compliance''.
On p. 17787	§ 1910.1200, paragraphs (d)(4), (d)(5), and (d)(6).	Remove paragraphs (d)(4), (d)(5), and (d)(6).
On p. 17791	§ 1910.1200, Appendix A, Table A.1.1 Note (a).	Remove the word ''Steward''.
On p. 17791	§ 1910.1200, Appendix A, Paragraph A.1.2, Table A.1.1.	Dermal Category 1 value of ''≤5'' is corrected to read ''≤50''.
On p. 17797	§ 1910.1200, Appendix A, Paragraph A.2.4.3.1.	The concentration of ''relevant ingredients'' of a mixture is corrected from ''>1%'' to ''≥1%''.
On p. 17801	§ 1910.1200, Appendix A, Paragraph A.3.4.3.1.	The concentration of ''relevant ingredients'' of a mixture is corrected from ''>1%'' to ''≥1%''.
On p. 17818	§ 1910.1200, Appendix B, Paragraph B.3.2, Table B.3.1.	Reformat table to clarify application of hazard categories.
On p. 17886	§ 1910.1200, Appendix F, Part A.	Correct the paragraph numbering in the first column. The second subsection under the heading *Carcinogenicity in experimental animals* is corrected to read ''(b)''.
On p. 17887	§ 1910.1200, Appendix F, Part D.	The NTP RoC column of the Table is corrected to indicate that the text ''Reasonably Anticipated (See Note 1)'' is intended to refer to both lines (IARC Group 2A and 2B, and GHS Category 1B and 2), and the subparagraphs in paragraph 3 of Note 1 are corrected to ''a'' and ''b'' rather than ''c'' and ''d''.
On p. 17888	§ 1915.1001, Appendix K ...	''material safety data sheet'' and the acronym ''MSDS'' are corrected to ''safety data sheet'' and ''SDS'', respectively.
On p. 17890	§ 1926.64, Appendix C	''material safety data sheet'' and the acronym ''MSDS'' are corrected to ''safety data sheet'' and ''SDS'', respectively.
On p. 17890	§ 1926.65, Appendix E	''material safety data sheet'' is corrected to ''safety data sheet''.
On p. 17895	§ 1926.1101, paragraph (k)(8)(v).	Paragraphs (k)(8)(iv)(B) and (k)(8)(v) are repetitive; paragraph (k)(8)(v) is designated as ''Reserved.''

II. Exemption From Notice-and-Comment Procedures

Section 4 of the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), provides that, when an Agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the Agency may issue a final rule without providing notice and an opportunity for public comment. This rulemaking only corrects errors of a minor, mainly typographical nature and therefore does not affect or change any existing rights or obligations. OSHA has determined that there is good cause, pursuant to 5 U.S.C. 553(b)(3)(B), Section 6(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655(b)), and 29 CFR 1911.5, for making this correctional amendment final without prior proposal and opportunity for comment because the rulemaking does not affect or change any existing rights or obligations, and no stakeholder is likely to object to them. For the same reasons, the Agency finds good cause under 5 U.S.C. 553(d)(3) to make the amendment effective upon publication.

III. Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, authorized the preparation of this document. It is issued under the authority of sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); 5 U.S.C. 553; Section 304, Clean Air Act Amendments of 1990 (Pub. L. 101–549, reprinted at 29 U.S.C.A. 655 Note); Section 41, Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941); Section 107, Contract Work Hours and Safety Standards Act (40 U.S.C. 3704); Section 1031, Housing and Community Development Act of 1992 (42 U.S.C. 4853); Section 126, Superfund Amendments and Reauthorization Act of 1986, as

amended (reprinted at 29 U.S.C.A. 655 Note); Secretary of Labor's Order No. 1–2012 (77 FR 3912); and 29 CFR Part 1911.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

List of Subjects

29 CFR Part 1910

Asbestos, Chemicals, Fire prevention, Hazard communication, Hazardous substances, Occupational safety and health.

29 CFR Part 1915

Asbestos, Longshore and harbor workers, Occupational safety and health.

29 CFR Part 1926

Asbestos, Construction industry, Fire prevention, Hazardous substances, Occupational safety and health.

Accordingly, OSHA is amending 29 CFR parts 1910, 1915, and 1926 by making the following corrections and technical amendments:

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Subpart H—[Amended]

■ 1. The authority citation for Part 1910 Subpart H continues to read as follows:

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), or 5–2007 (72 FR 31159), 4–2010 (75 FR 55355) or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.

Sections 1910.103, 1910.106 through 1910.111, and 1910.119, 1910.120, and 1910.122 through 1910.126 also issued under 29 CFR part 1911.

Section 1910.119 also issued under Section 304, Clean Air Act Amendments of 1990 (Pub. L. 101–549), reprinted at 29 U.S.C.A. 655 Note.

Section 1910.120 also issued under Section 126, Superfund Amendments and Reauthorization Act of 1986 as amended (29 U.S.C.A. 655 Note), and 5 U.S.C. 553.

§ 1910.119 [Amended]

■ 2. Amend § 1910.119 as follows:
■ a. Remove the words ''Material Safety Data Sheets'' and add in their place ''safety data sheets'' in the note following paragraph (d)(1).
■ b. In Appendix C to § 1910.119, remove ''material safety data sheet (MSDS)'' in the second paragraph in section 3 and add in its place ''safety data sheet (SDS)'' and remove ''MSDS'' in the first paragraph in section 6 and add in its place ''SDSs''.
■ c. In Appendix C to § 1910.119, remove the words ''material safety data sheets'' and add in their place ''safety data sheets'' in the seventh paragraph in section 13.

§ 1910.120 [Amended]

■ 3. Amend § 1910.120:
■ a. By removing the acronym ''MSDS'' and adding in its place ''SDS'' wherever it appears; and
■ b. In Appendix E to § 1910.120, by removing the words ''material safety data sheets'' and adding in their place ''safety data sheets'' wherever they appear.

Subpart Z—[Amended]

■ 4. The authority citation for Part 1910 Subpart Z continues to read as follows:

Authority: Sections 4, 6, 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31159), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.

All of subpart Z issued under section 6(b) of the Occupational Safety and Health Act of 1970, except those substances that have exposure limits listed in Tables Z–1, Z–2, and Z–3 of 29 CFR 1910.1000. The latter were issued under section 6(a) (29 U.S.C. 655(a)).

Section 1910.1000, Tables Z–1, Z–2 and Z–3 also issued under 5 U.S.C. 553, but not under 29 CFR part 1911 except for the arsenic (organic compounds), benzene, cotton dust, and chromium (VI) listings.

Section 1910.1001 also issued under section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3704) and 5 U.S.C. 553.

Section 1910.1002 also issued under 5 U.S.C. 553, but not under 29 U.S.C. 655 or 29 CFR part 1911.

Sections 1910.1018, 1910.1029, and 1910.1200 also issued under 29 U.S.C. 653.

Section 1910.1030 also issued under Pub. L. 106–430, 114 Stat. 1901.

Section 1910.1201 also issued under 49 U.S.C. 1801–1819 and 5 U.S.C. 533.

§ 1910.1001 [Amended]

■ 5. Amend § 1910.1001 as follows:
■ a. Remove the words ''material safety data sheet'' and add in their place ''safety data sheet'' wherever they appear in Appendix J;
■ b. Remove the acronym ''MSDS'' and add in its place ''SDS'' wherever it appears in Appendix J.

§ 1910.1044 [Amended]

■ 6. Amend § 1910.1044 as follows:
■ a. Remove the phrase ''Class IIIA combustible liquid'' and add in its place ''Category 4 flammable liquid'' wherever it appears in Appendix B.

§ 1910.1048 [Amended]

■ 7. Amend § 1910.1048 by removing the phrase ''Flammability Class (OSHA): III A'' and adding in its place ''Flammability (OSHA): Category 4 flammable liquid'' wherever it appears in Appendix A.
■ 8. Amend § 1910.1051 by revising paragraph (l)(1)(ii) to read as follows:

§ 1910.1051 1,3-Butadiene.

* * * * *

(l) * * *

(1) * * *

(ii) In classifying the hazards of BD at least the following hazards are to be addressed: Cancer; eye and respiratory tract irritation; central nervous system effects; and flammability.

* * * * *

■ 9. Amend § 1910.1052, in Appendix A, by revising paragraph E in section X to read as follows:

§ 1910.1052 Methylene Chloride.

* * * * *

Appendix A to § 1910.1052—Substance Safety Data Sheet and Technical Guidelines for Methylene Chloride

* * * * *

X. Access to Information

* * * * *

E. Your employer is required to provide labels and safety data sheets (SDSs) for all materials, mixtures or solutions composed of greater than 0.1 percent MC. These materials, mixtures or solutions would be classified and labeled in accordance with § 1910.1200.

* * * * *

■ 10. Amend § 1910.1200 as follows:
■ a. Remove paragraphs (d)(4) through (6).
■ b. Remove the word ''Steward'' in Appendix A, Table A.1.1 Note (a).
■ c. Remove the value of ''≤5'' and add in its place ''≤50'' for Dermal Category 1 in Appendix A, paragraph A.1.2, Table A.1.1.
■ d. In Appendix A, revise paragraphs A.2.4.3.1 and A.3.4.3.1.
■ e. In Appendix B, in paragraph B.3.2, revise Table B.3.1.
■ f. Remove the second occurrence of Appendix E (entitled ''(Advisory)—Guidelines for Employer Compliance'').
■ g. In Appendix F, in Part A, redesignate the second paragraph (a) under ''carcinogenicity in experimental animals'' as paragraph (b) and revise Part D.

The revisions read as follows:

§ 1910.1200 Hazard Communication.

* * * * *

Appendix A to § 1910.1200—Health Hazard Criteria (Mandatory)

* * * * *

A.1 ACUTE TOXICITY

* * * * *

TABLE A.1.1—ACUTE TOXICITY HAZARD CATEGORIES AND ACUTE TOXICITY ESTIMATE (ATE) VALUES DEFINING THE RESPECTIVE CATEGORIES

Exposure route	Category 1	Category 2	Category 3	Category 4
Oral (mg/kg bodyweight) *see: Note (a)* *Note (b)*	≤ 5	>5 and ≤ 50	>50 and ≤ 300	>300 and ≤ 2000.
Dermal (mg/kg bodyweight) *see: Note (a)* *Note (b)*	≤ 50	>50 and ≤ 200	>200 and ≤ 1000	>1000 and ≤ 2000.
Inhalation—Gases (ppmV) *see: Note (a)* *Note (b)* *Note (c)*	≤ 100	>100 and ≤ 500	>500 and ≤ 2500	>2500 and ≤ 20000.
Inhalation—Vapors (mg/l) *see: Note (a)* *Note (b)* *Note (c)* *Note (d)*	≤ 0.5	>0.5 and ≤ 2.0	>2.0 and ≤ 10.0	>10.0 and ≤ 20.0.
Inhalation—Dusts and Mists (mg/l) *see: Note (a)* *Note (b)* *Note (c)*	≤ 0.05	>0.05 and ≤ 0.5	>0.5 and ≤ 1.0	>1.0 and ≤ 5.0.

* * * * *

A.2 SKIN CORROSION/IRRITATION

* * * * *

A.2.4

* * *

A.2.4.3

* * *

A.2.4.3.1. For purposes of classifying the skin corrosion/irritation hazards of mixtures in the tiered approach:

The ''relevant ingredients'' of a mixture are those which are present in concentrations ≥1% (weight/weight for solids, liquids, dusts, mists and vapors and volume/volume for gases.) If the classifier has reason to suspect that an ingredient present at a concentration <1% will affect classification of the mixture for skin corrosion/irritation, that ingredient shall also be considered relevant.

* * * * *

A.3 SERIOUS EYE DAMAGE/EYE IRRITATION

* * * * *

A.3.4 * * *

A.3.4.3 * * *

A.3.4.3.1 For purposes of classifying the eye corrosion/irritation hazards of mixtures in the tiered approach:

The ''relevant ingredients'' of a mixture are those which are present in concentrations ≥1% (weight/weight for solids, liquids, dusts, mists and vapors and volume/volume for gases.) If the classifier has reason to suspect that an ingredient present at a concentration <1% will affect classification of the mixture for eye corrosion/irritation, that ingredient shall also be considered relevant.

* * * * *

Appendix B to § 1910.1200—Physical Hazard Criteria (Mandatory)

* * * * *

B.3 FLAMMABLE AEROSOLS

* * * * *

B.3.2 Classification Criteria

* * * * *

TABLE B.3.1—CRITERIA FOR FLAMMABLE AEROSOLS

Category	Criteria
1	Contains ≥ 85% flammable components and the chemical heat of combustion is ≥ 30 kJ/g; or (a) For spray aerosols, in the ignition distance test, ignition occurs at a distance ≥ 75 cm (29.5 in), or (b) For foam aerosols, in the aerosol foam flammability test (i) The flame height is ≥ 20 cm (7.87 in) and the flame duration ≥ 2 s; or (ii) The flame height is ≥ 4 cm (1.57 in) and the flame duration ≥ 7 s
2	Contains > 1% flammable components, or the heat of combustion is ≥ 20 kJ/g; and (a) for spray aerosols, in the ignition distance test, ignition occurs at a distance ≥ 15 cm (5.9 in), or in the enclosed space ignition test, the (i) Time equivalent is ≤ 300 s/m^3; or (ii) Deflagration density is ≤ 300 g/m^3 (b) For foam aerosols, in the aerosol foam flammability test, the flame height is ≥ 4 cm and the flame duration is ≥ 2 s and it does not meet the criteria for Category 1

* * * * *

Appendix F to § 1910.1200—Guidance for Hazard Classifications Re: Carcinogenicity (Non-Mandatory)

* * * * *

Part D: Table Relating Approximate Equivalences Among IARC, NTP RoC, and GHS Carcinogenicity Classifications

The following table may be used to perform hazard classifications for carcinogenicity under the HCS (§ 1910.1200). It relates the approximated GHS hazard categories for carcinogenicity to the classifications provided by IARC and NTP, as described in Parts B and C of this Appendix.

APPROXIMATE EQUIVALENCES AMONG CARCINOGEN CLASSIFICATION SCHEMES

IARC	GHS	NTP RoC
Group 1	Category 1A	Known.
Group 2A	Category 1B	Reasonably Anticipated (See Note 1).
Group 2B	Category 2	Reasonably Anticipated (See Note 1).

Note 1:

1. *Limited evidence of carcinogenicity from studies in humans (corresponding to IARC 2A/GHS 1B);*

2. *Sufficient evidence of carcinogenicity from studies in experimental animals (again, essentially corresponding to IARC 2A/GHS 1B);*

3. *Less than sufficient evidence of carcinogenicity in humans or laboratory animals; however:*

a. *The agent, substance, or mixture belongs to a well-defined, structurally-related class of substances whose members are listed in a previous RoC as either ''Known'' or ''Reasonably Anticipated'' to be a human carcinogen, or*

b. *There is convincing relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans.*

* * * * *

PART 1915—OCCUPATIONAL SAFETY AND HEALTH STANDARDS FOR SHIPYARD EMPLOYMENT

Subpart Z—[Amended]

■ 11. The authority citation for Part 1915 continues to read as follows:

Authority: Section 41, Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941); Sections. 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable; and 29 CFR Part 1911.

Section 1915.100 also issued under 49 U.S.C. 1801–1819 and 5 U.S.C. 553.

Sections 1915.120 and 1915.152 of 29 CFR also issued under 29 CFR part 1911.

§ 1915.1001 [Amended]

■ 12. Amend § 1915.1001 by removing the words ''Material Safety Data Sheet'' and adding in their place ''safety data sheet'' and removing the acronym ''MSDS'' and adding in its place ''SDS'' in Appendix K, section 3.1.(e).

PART 1926—OCCUPATIONAL SAFETY AND HEALTH STANDARDS FOR CONSTRUCTION

Subpart D—[Amended]

■ 13. The authority citation for Part 1926 Subpart D continues to read as follows:

Authority: Section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3704); Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, and 657); and Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31159), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912) as applicable; and 29 CFR part 1911.

Sections 1926.58, 1926.59, 1926.60, and 1926.65 also issued under 5 U.S.C. 553 and 29 CFR part 1911.

Section 1926.61 also issued under 49 U.S.C. 1801–1819 and 6 U.S.C. 553.

Section 1926.62 also issued under section 1031 of the Housing and Community Development Act of 1992 (42 U.S.C. 4853).

Section 1926.65 also issued under section 126 of the Superfund Amendments and Reauthorization Act of 1986, as amended (reprinted at 29 U.S.C.A. 655 Note), and 5 U.S.C. 553.

§ 1926.64 [Amended]

■ 14. Amend § 1926.64 as follows:
■ a. Remove the words ''material safety data sheet'' and add in their place ''safety data sheet'' wherever they appear in Appendix C;
■ b. Remove the words ''material safety data sheets'' and add in their place ''safety data sheets'' wherever they appear in Appendix C;
■ c. Remove the acronym ''MSDS'' and add in its place ''SDS'' wherever it appears in Appendix C.

§ 1926.65 [Amended]

■ 15. Amend § 1926.65 by removing the words ''material safety data sheets'' and adding in their place ''safety data sheets'' wherever they appear in Appendix E.

Subpart Z—[Amended]

■ 16. The authority citation for Part 1926 Subpart Z continues to read as follows:

Authority: Section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3704); Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); and Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31159), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912) as applicable; and 29 CFR part 1911.

Section 1926.1102 not issued under 29 U.S.C. 655 or 29 CFR part 1911; also issued under 5 U.S.C. 553.

§ 1926.1101 [Amended]

■ 17. Amend § 1926.1101 remove and reserve paragraph (k)(8)(v).

[FR Doc. 2013–01416 Filed 2–7–13; 8:45 am]

BILLING CODE 4510–26–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2013–0013; FRL–9777–5]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Removal of the Mount Saint Mary's College 1979 Consent Order

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve a State Implementation Plan (SIP) revision submitted by the Maryland Department of the Environment (MDE) pertaining to the F. Keeler Company Boiler at Mount Saint Mary's College. This revision removes the Mount Saint Mary's College 1979 Consent Order (1979 Consent Order) from the Maryland SIP because the coal-fired F. Keeler Boiler has been modified by removing the coal-firing capability and converting the boiler to fire natural gas with No. 2 fuel oil as backup. EPA is approving this SIP revision because the 1979 Consent Order is no longer required as the modified gas-fired unit can comply with all visible emission and particulate requirements in the Maryland SIP, and this 1979 Consent Order is no longer required to satisfy any applicable Federal regulations or the Clean Air Act (CAA). This action is being taken under the CAA.

DATES: This rule is effective on April 9, 2013 without further notice, unless EPA receives adverse written comment by March 11, 2013. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2013–0013 by one of the following methods:

A. *www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. *Email: mastro.donna@epa.gov.*

C. *Mail:* EPA–R03–OAR–2013–0013, Donna Mastro, Acting Associate Director, (215) 814–2777, Air Protection Division, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2013–0013. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland 21230.

FOR FURTHER INFORMATION CONTACT: Maria Pino, Air Protection Division, Project officer, (215) 814–2181, or by email at *pino.maria@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The 1979 Consent Order provided an exception to Maryland's fuel burning regulations for Mount Saint Mary's College to allow the construction of a 25 million British Thermal Units (BTU) per hour coal-fired boiler. The specific regulations of concern for the coal-fired boiler at Mount Saint Mary's College were: COMAR 10.18.03.02B (requirement for zero visible emissions); COMAR 10.18.03.03B(2)b (requirement that particulate matter (PM) not exceed 0.03 grains per dry standard cubic foot (gr/dscf)); COMAR 10.18.03.03B(2)c(2) (requirement for dust collectors); and COMAR 10.18.03.06D(2) (prohibition of small solid-fuel boilers). MDE approved the construction of the coal-fired boiler because the coal-fired boiler was in a rural area and minimal impact on air quality was expected from particulate emissions from the boiler. The boiler was required to meet COMAR 10.18.03.02A (requirement not to exceed 20% opacity) and COMAR 10.18.03.03B(3) (requirement that PM emissions not exceed 0.10 gr/dscf). The 1979 Consent Order between Mount Saint Mary's College and Maryland was approved by EPA into the Maryland SIP on March 18, 1980. 45 FR 17144 (approving the 1979 Consent Order into Maryland SIP because no ambient air quality standards would be violated by operation of the boiler). Subsequently, in January 1983, Mount Saint Mary's College installed multicyclones on the boiler for additional control of PM.

II. Summary of the SIP Revision

On November 19, 2012, MDE submitted a revision (#12–05) to remove the 1979 Consent Order from Maryland's SIP because the coal-fired F. Keeler Boiler has been converted to fire natural gas with No. 2 fuel oil as backup. On July 18, 2000, MDE issued a permit to convert the boiler to natural gas with No. 2 oil as backup fuel. The converted gas-fired boiler is able to comply with all Maryland regulations, including visible emissions standards. Therefore, the 1979 Consent Order is no longer required and MDE has requested that it be removed from the Maryland SIP.

III. Final Action

EPA's review of the SIP revision submitted by MDE on November 19, 2012 indicates that the 1979 Consent Order is no longer required as the modified gas-fired boiler is able to comply with all applicable Federal regulations and the Maryland SIP. Therefore, EPA is approving the SIP revision submitted by MDE on November 19, 2012 to remove the 1979 Consent Order. The 1979 Consent Order is no longer required to satisfy any applicable Federal regulations or the CAA. EPA is publishing this rule without prior proposal because EPA views this as a noncontroversial amendment and anticipates no adverse comment. However, in the ''Proposed Rules'' section of today's **Federal Register**, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision if adverse comments are filed. This rule will be effective on April 9, 2013 without further notice unless EPA receives adverse comment by March 11, 2013. If EPA receives adverse comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rulemaking action based on the proposed rule. EPA will not institute a second comment period on this rulemaking action. Any parties interested in commenting must do so at this time.

IV. Statutory and Executive Order Reviews

A. General Requirements

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of

the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

B. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 804, however, exempts from section 801 the following types of rules: rules of particular applicability; rules relating to agency management or personnel; and rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. 804(3). Because this is a rule of particular applicability, EPA is not required to submit a rule report regarding this action under section 801.

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 9, 2013. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register,** rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking.

This action to approve a revision to the Maryland SIP to remove the Mount Saint Mary's College 1979 Consent Order from the SIP may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Particulate matter.

Dated: January 25, 2013.

W.C. Early,

Acting Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart V—Maryland

§ 52.1070 [Amended]

■ 2. In § 52.1070, the table in paragraph (d) is amended by removing the entry for Mt. Saint Mary's College.

[FR Doc. 2013–02817 Filed 2–7–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2012–0795; FRL–9376–4]

Glycine max Herbicide-Resistant Acetolactate Synthase; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the *Glycine max* herbicide-resistant acetolactate synthase (GM–HRA) enzyme when used as a plant-incorporated protectant inert ingredient in or on the food and feed commodities of soybean. Pioneer Hi-Bred International, Inc. (DuPont Pioneer), submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Glycine max* herbicide-resistant acetolactate synthase enzyme in or on the food and feed commodities of soybean.

DATES: This regulation is effective February 8, 2013. Objections and requests for hearings must be received on or before April 9, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0795, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review

the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Susanne Cerrelli, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8077; email address: *cerrelli.susanne@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 174 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2012–0795 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 9, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2012–0795, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Background and Statutory Findings

In the **Federal Register** of November 7, 2012 (77 FR 66781) (FRL–9367–5), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 2E8059) by Pioneer Hi-Bred International, Inc. (DuPont Pioneer), 7100 NW., 62nd Avenue, P.O. Box 1000, Johnston, Iowa, 50131. The petition requested that 40 CFR part 174 be amended by establishing an exemption from the requirement of a tolerance for residues of *Glycine max* herbicide-resistant acetolactate synthase (GM–HRA) when used as a plant-incorporated protectant (PIP) inert ingredient in or on the food and feed commodities of soybean. That document referenced a summary of the petition prepared by the petitioner, Pioneer Hi-Bred International, Inc. (DuPont Pioneer), which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue * * *.'' Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider ''available information concerning the cumulative effects of a particular pesticide's residues'' and ''other substances that have a common mechanism of toxicity.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability, and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

A. Product Characterization Overview

Acetolactate synthase (ALS) protein, also known as acetohydroxyacid synthase (AHAS), is a key enzyme that catalyzes the first common step in the biosynthesis of the essential branched-chain amino acids, and is obligatory for plant development. The gene that encodes the GM–HRA protein, *gm-hra,* is derived from the *gm-als I* gene, a naturally occurring soybean gene that encodes for acetolactate synthase I (GM–ALS I) protein. Changes were made in the DNA gene sequence for *gm-als I* to produce *gm-hra.* The modified gene was then introduced into the plant's genome through particle bombardment (with the PHP30987A fragment). The GM–HRA

protein is 604 amino acids in length, with a predicted molecular weight of 65 kilodaltons (kDa), and is >99% homologous with the native GM–ALS I protein produced in soybeans. This minor modification of the endogenous GM–ALS I protein to GM–HRA protein yields an enzyme that is resistant to ALS-inhibiting herbicides. Thus, the GM–HRA protein will be useful as a selectable marker in soybean transformation events. As part of a genetic construct introduced into a plant's genome, GM–HRA itself does not have insecticidal activity and is therefore functionally inert as part of a PIP. Potentially, GM–HRA also might serve as an herbicide-tolerant trait in soybeans, a use over which the U.S. Department of Agriculture (USDA) has separate regulatory jurisdiction.

B. Mammalian Toxicity Assessment

DuPont Pioneer, has submitted acute oral toxicity data demonstrating the lack of mammalian toxicity at relatively high levels of exposure to the pure GM–HRA protein. These data demonstrate the safety of the product at a level well above maximum possible exposure levels that are reasonably anticipated in the crop (Ref. 1).

An acute oral toxicity study in mice indicated that GM–HRA is nontoxic (Ref. 2). Two groups of five males and five females mice were orally dosed (via gavage) with 2,000 milligrams/kilograms body weight (mg/kg bwt) of the test substance, a biochemically and functionally equivalent, microbially produced GM–HRA protein. There were no adverse clinical signs or findings at necropsy in the test animals.

When proteins are toxic, they are known to act *via* acute mechanisms and at very low dose levels (Ref. 3). Since no acute oral effects were shown to be caused by GM–HRA, even at relatively high dose levels (up to 2,000 mg/kg bwt), the GM–HRA protein is not considered to be toxic. In support of this conclusion, amino acid sequence comparisons between the GM–HRA protein and known toxic proteins in protein databases found no similarities that would contradict the results of the acute oral study.

C. Allergenicity Assessment

Since GM–HRA is a protein, allergenic sensitivities were considered. Currently, no definitive tests exist for determining the allergenic potential of novel proteins. Current scientific knowledge suggests that common food allergens tend to be resistant to degradation by acid and proteases; they also may be glycosylated, and are present at high concentrations in food. Using a ''weight-of-evidence'' approach, EPA considered the source of the trait, amino acid sequence similarity with known allergens, its prevalence in food, and biochemical properties of the protein, including *in vitro* digestibility in simulated gastric fluid (SGF), and glycosylation (Ref. 4). The results of the EPA's analysis are as follows:

1. *Source of the trait.* The donor organism is *Glycine max* (soybean), which has an endogenous gene (*gm-als I*) that encodes for acetolactate synthase I (GM–ALS I) protein. Although soybean is one of the major food allergens, none of the known soy allergens is a member of the ALS protein family, including ALS protein. ALS enzymes are widely distributed in nature, and *als* genes have been isolated from bacteria, fungi, algae and plants (Refs. 5, 6, 7, and 8). Amino acid sequencing (BLASTP analysis) yielded 12,451 structurally or functionally related protein accessions (Ref. 9).The *gm-hra* gene, coding for the proposed PIP inert ingredient GM–HRA protein, was produced by transforming the naturally occurring, herbicide-sensitive *gm-als I* genetic sequence. The new gene was introduced into the plant, and the resulting herbicide-tolerant GM–HRA protein differs from the ALS I protein by only two amino acids. Both of the two amino acid substitutions in GM–HRA are already present in commercially available crop varieties (soybean, sunflower, maize, and canola (Refs. 10, 11, 12 and 13)) that are naturally tolerant to ALS-inhibiting herbicides.

2. *Amino acid sequence.* A comparison of the amino acid sequence of GM–HRA with known allergens found no significant overall sequence similarity or identity at the level of eight contiguous amino acid residues, the level of sensitivity needed to detect potential allergens.

3. *Prevalence in food.* ALS enzymes have been part of the human diet by virtue of their presence in soybeans and other commercial food crops (soybean, maize, wheat, rice, and canola). Some of these enzymes contain natural mutations that include the same two amino acid substitutions as GM–HRA protein that render them tolerant to ALS-inhibiting herbicides (Ref. 12), and no ALS-related food allergies have been reported.

4. *Digestibility.* The GM–HRA protein was rapidly digested (in less than 30 seconds) in simulated mammalian gastric fluid (which has a highly acidic pH of 1.2 and includes the protein digesting enzyme, pepsin, found in gastric fluid) after incubation at 37 °C.

5. *Glycosylation.* The GM–HRA protein expressed in soybean is not glycosylated. Considering all of the available information, EPA has concluded that the potential for GM–HRA to be a food allergen is minimal.

IV. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

The Agency has considered available information on the aggregate exposure levels of consumers and major identifiable subgroups of consumers, including infants and children, to the proposed pesticide PIP inert residue, GM–HRA protein, and to other related substances. This protein is an enzyme produced in soybean by a gene that was genetically derived from a naturally occurring soybean gene that encodes an herbicide-sensitive ALS enzyme. The altered gene is reinserted into soybean, and the resulting GM–HRA protein has greater than 99% similarity with the natural herbicide-sensitive protein enzyme, differing only in two amino acids (Ref. 13). These minor changes confer resistance of the enzyme to herbicidal pesticides that inhibit ALS enzymes, which is what allows the GM–HRA protein to be used as a selectable herbicide-tolerant marker in soybean transformation events. The two amino acid substitutions found in the engineered GM–HRA protein also occur as natural mutations in other commercially available, non-genetically modified crop varieties that are tolerant to ALS-inhibiting herbicides, and thus human exposure to the naturally occurring protein, in addition to the proposed PIP inert, is anticipated. The only route of human exposure that is likely, however, is through the human diet, since the proposed PIP inert ingredient (and the related naturally occurring ALS enzymes) is contained within plant cells, which reduces potential human exposure via other routes to negligible. Exposure *via* residential or lawn use is not expected because the intended use sites are all agricultural. Though highly unlikely, should residues of GM–HRA appear in drinking water as a result of its use as a PIP inert ingredient in soybean, the risk to humans would be very unlikely, based on the protein's lack of mammalian toxicity demonstrated in the acute oral toxicity study and the lack of amino acid similarity with

known protein toxins and allergens (see Unit III).

V. Cumulative Effects From Substances With a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Based on the results of acute toxicity testing, EPA concluded that the proposed PIP inert, GM–HRA, is not toxic. EPA also concluded that no toxic or allergenic metabolites are produced in soybean or other edible crops from the activity of this catabolic enzyme. In addition, GM–HRA as encoded by the *gm-hra* gene was previously evaluated for its safety by the U.S. Food and Drug Administration (FDA) in two other transgenic soybean events. In one event, the gene was modified to produce high oleic soybean oil (OECD Unique ID No. DP–3Ø5423–1), and the other provided glyphosate and ALS-inhibiting herbicide tolerance (OECD Unique ID No. DP–356Ø43–5) (Refs.14 and 15). Based upon the information submitted, FDA concluded that the safety profiles of these soybean events, the GM–HRA protein were not materially different from that of other marketed soybean varieties, and no safety concerns with the protein were identified (Refs.16 and 17).

EPA concludes that there are no cumulative effects associated with GM–HRA expected from the proposed use as a PIP inert ingredient in soybean. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

VI. Determination of Safety for U.S. Population, Infants and Children

The data submitted and cited regarding potential health effects for the GM–HRA protein include the characterization of the expressed GM–HRA protein in soybean, as well as the acute oral toxicity, amino acid sequence comparisons, and *in vitro* digestibility study. The results of these studies were used to evaluate human risk, and the validity, completeness, and reliability of the available data from the studies was considered.

As discussed in unit III, the acute oral toxicity data submitted supports the prediction that the GM–HRA protein would be nontoxic to humans. Moreover, amino acid sequence analysis demonstrated that GM–HRA was not similar to any known protein toxin or allergen. Other data considered as part of the allergenicity assessment included: The structural and functional similarity of GM–HRA protein with naturally occurring ALS proteins from soybean and other food crops; the ALS proteins are not associated with food allergenicity; the protein rapidly degraded in the highly acidic digestibility study; and GM–HRA protein not glycosylated when expressed in the plant. GM–HRA protein is therefore not expected to be a human allergen.

Finally, and specifically with regard to infants and children, FFDCA section 408(b)(2)(C) provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children.

Based on its review and consideration of all the available information, the Agency concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of the GM–HRA protein and the genetic material necessary for its production when used as a PIP inert ingredient in or on food and feed commodities of soybean. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has also concluded, for the reasons discussed in more detail above, that there are no threshold effects of concern and, as a result, that an additional margin of safety for infants and children is unnecessary in this instance.

VII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for GM–HRA protein in soybean.

VIII. Conclusions

Therefore, an exemption from the requirement of a tolerance is established for residues of *Glycine max* herbicide-resistant acetolactate synthase (GM–HRA) enzyme in or on the food and feed commodities of soybean when used as a plant-incorporated protectant inert ingredient.

IX. References

1. U.S. EPA. 2012. Review of Product Characterization and Human Health Data for *Glycine max* Herbicide-Tolerant Acetolactate Synthase (GM–HRA) protein expressed in Event 82117 soybean (OECD Unique ID. DP–Ø82117–3) in support of an Exemption from the Requirement of a Tolerance (Petition No. 2E8059) when used as a Plant-Incorporated Protectant (PIP) Inert Ingredient in soybean. Memorandum from A. Waggoner, and J. Kough, Ph.D. to S. Cerrelli. (Dated December 20, 2012).
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X. Statutory and Executive Order Reviews

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

XI. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 174

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 17, 2013.

Steven Bradbury,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 174—[AMENDED]

■ 1. The authority citation for part 174 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Add § 174.533 to subpart W to read as follows:

§ 174.533 *Glycine max* Herbicide-Resistant Acetolactate Synthase (GM–HRA) inert ingredient; exemption from the requirement of a tolerance.

Residues of *Glycine max* herbicide-resistant acetolactate synthase (GM–HRA) enzyme in or on the food and feed commodities of soybean are exempt from the requirement of a tolerance when used as a plant-incorporated protectant inert ingredient.

[FR Doc. 2013–02699 Filed 2–7–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0916; FRL–9376–9]

Hexythiazox; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of hexythiazox in or on alfalfa and timothy. Gowan Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 8, 2013. Objections and requests for hearings must be received on or before April 9, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2010–0916, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Olga Odiott, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–9369; email address: *odiott.olga@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* If OCSPP test guidelines are cited, insert the following: To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0916 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 9, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0916, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of March 14, 2012 (77 FR 15012) (FRL–9335–9), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F7934) by Gowan Company, 370 South Main Street, Yuma, AZ 85364. The petition requested that 40 CFR 180.448 be amended by establishing tolerances for residues of the insecticide hexythiazox (trans-5-(4-chlorophenyl)-*N*-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide) and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety, in or on wheat, forage at 3.0 parts per million (ppm); wheat, hay at 30 ppm; wheat, grain at 0.02 ppm; wheat, straw at 7.0 ppm; alfalfa, forage at 7.0 ppm; alfalfa, hay at 14 ppm; timothy, forage at 35 ppm; and timothy, hay at 17 ppm. That document referenced a summary of the petition prepared by Gowan Company, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based on EPA's review of the data supporting the petition, Gowan Company revised their petition (PP 1F7934) as follows:

i. By increasing the proposed tolerances for alfalfa, forage; alfalfa, hay; timothy forage; and timothy, hay;

ii. By deleting the proposed tolerances for wheat commodities;

iii. By adding a request for an increase in the established tolerances for cattle, fat; goat, fat; horse fat; sheep fat; and milk;

iv. By adding a request for an increase in the established tolerances for cattle meat byproducts; goat, meat byproducts; horse, meat byproducts; and sheep, meat byproducts; and;

v. By proposing tolerances for poultry, fat; and poultry, meat byproducts; and egg.

The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue * * *.''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for hexythiazox including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with hexythiazox follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The toxicity database for hexythiazox is complete. Hexythiazox has low acute toxicity by the oral, dermal and inhalation routes of exposure. It produces mild eye irritation, is not a dermal irritant, and is negative for dermal sensitization. Hexythiazox is associated with toxicity of the liver and adrenals following subchronic and chronic exposure to dogs, rats and mice, with the dog being the most sensitive species. The prenatal developmental studies in rabbits and rats and the two-generation reproduction study in rats showed no indication of increased susceptibility to *in utero* and/or postnatal exposure to hexythiazox. Reproductive toxicity was not observed. There is no concern for immunotoxicity or neurotoxicity following exposure to hexythiazox. The toxicology database for hexythiazox does not show any evidence of treatment-related effects on the immune system. Hexythiazox is classified as ''likely to be carcinogenic to humans''; however, the evidence as a whole is not strong enough to warrant a quantitative estimation of human risk. Since the effects seen in the study that serves as the basis for the chronic RfD occurred at doses substantially below the lowest dose that induced tumors, the chronic RfD is considered protective of all chronic effects including potential carcinogenicity.

Specific information on the studies received and the nature of the adverse effects caused by hexythiazox as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document ''Hexythiazox. Human Health Risk Assessment to Support New Uses on Alfalfa and Timothy'' in docket ID number EPA–HQ–OPP–2010–0916.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for hexythiazox used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR HEXYTHIAZOX FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations).	No risk is expected from this exposure scenario as no hazard was identified in any toxicity study for this duration of exposure.		
Chronic dietary (All populations).	NOAEL = 2.5 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.025 mg/kg/day. cPAD = 0.025	One-Year Toxicity Feeding Study—Dog. LOAEL = 12.5 mg/kg/day based on increased absolute and relative adrenal weights and associated adrenal histopathology.
Incidental oral short-term (1 to 30 days) and intermediate-term (1 to 6 months).	NOAEL = 30 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100 ...	2-Generation Reproduction Study—Rat. LOAEL = 180 mg/kg/day based on decreased pup body weight during lactation and delayed hair growth and/or eye opening, and decreased parental body-weight gain and increased absolute and relative liver, kidney, and adrenal weights.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR HEXYTHIAZOX FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
			13-Week Oral Toxicity Study—Rat. NOAEL = 5.5 mg/kg/day. LOAEL = 38 mg/kg/day, based on increased absolute and relative liver weights in both sexes, increased relative ovarian and kidney weights, and fatty degeneration of the adrenal zona fasciculata. @ 397.5/257.6 mg/kg/day, decreased body-weight gain in females, slight swelling of hepatocytes in central zone (both sexes), increased incidence of glomerulonephrosis in males, increased adrenal weights.
Cancer (oral, dermal, inhalation).	Classification: ''Likely to be Carcinogenic to Humans''. Insufficient evidence to warrant a quantitative estimation of human risk using a cancer slope factor based on the common liver tumors (benign and malignant) observed only in high dose female mice, and benign mammary gland tumors of no biological significance, observed only in high dose male rats in the absence of mutagenic concerns. The chronic RfD is protective of all chronic effects including potential carcinogenicity of hexythiazox.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to hexythiazox, EPA considered exposure under the petitioned-for tolerances as well as all existing hexythiazox tolerances in 40 CFR 180.448. EPA assessed dietary exposures from hexythiazox in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for hexythiazox; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA used tolerance level residues, assumed 100 percent crop treated (PCT), and incorporated DEEM default processing factors when processing data were not available.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A. of the **Federal Register** of March 17, 2010 (75 FR 12691) (FRL–8813–7), EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to hexythiazox. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., *chronic exposure.*

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for hexythiazox. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for hexythiazox in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of hexythiazox. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), the estimated drinking water concentrations (EDWC) of hexythiazox for chronic exposures for non-cancer and cancer assessments are estimated to be 4.3 ppb for surface water. Since surface water residues values greatly exceed groundwater EDWCs, surface water residues were used in the dietary risk assessment. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Hexythiazox is currently registered for the following uses that could result in residential exposures: Ornamental plantings, turf, and fruit and nut trees in residential settings. EPA assessed residential exposure using the following assumptions: Residential handler exposures are expected to be short-term (1 to 30 days) via either the dermal or inhalation routes of exposures. Since a quantitative dermal risk assessment is not needed for hexythiazox; MOEs were calculated for the inhalation route of exposure only. Both adults and children may be exposed to hexythiazox residues from contact with treated lawns or treated residential plants. Post application exposures are expected to be short-term (1 to 30 days) and intermediate-term (1 to 6 months) in duration. Adult postapplication exposures were not assessed since no quantitative dermal risk assessment is needed for hexythiazox and inhalation exposures are typically negligible in outdoor settings. The exposure assessment for children included incidental oral exposure resulting from

transfer of residues from the hands or objects to the mouth, and from incidental ingestion of soil.

Details of the residential exposure and risk assessment can be found at *http://www.regulations.gov* in document ''Hexythiazox. Human Health Risk Assessment to Support New Uses on Alfalfa and Timothy'' in docket ID number EPA–HQ–OPP–2010–0916. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found hexythiazox to share a common mechanism of toxicity with any other substances, and hexythiazox does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that hexythiazox does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicology data base indicates no increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to hexythiazox.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for hexythiazox is complete.

ii. There is no indication that hexythiazox is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that hexythiazox results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. The dietary risk assessment is highly conservative and not expected to underestimate risk. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to hexythiazox in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by hexythiazox.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, hexythiazox is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to hexythiazox from food and water will utilize 63% of the cPAD for children 1–2 years of age, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of hexythiazox is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Hexythiazox is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to hexythiazox.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 12,000 for adults and 1,600 for children. Because EPA's level of concern for hexythiazox is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Hexythiazox is currently registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to hexythiazox.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 12,000 for adults and 1,900 for children. Because EPA's level of concern for hexythiazox is a MOE of 100 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population.* As discussed in Unit III.C.1.iii., EPA concluded that regulation based on the chronic reference dose will be protective for both chronic and carcinogenic risks. As noted in this unit there is no chronic risks of concern.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to hexythiazox residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high performance liquid chromatography method with UV detection (HPLC/UV) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

No Canadian or Mexican MRLs have been established for residues of hexythiazox in plants or livestock. There are no codex MRLs established for alfalfa or timothy; however, there are Code MRLs for livestock at 0.05 ppm in/on the following: edible offal (mammalian); mammalian fats (except milk fats); milks; milk fats; poultry, edible offal; poultry meat (fat). The U.S. and Codes residue definitions in both plants and livestock are harmonized. There is no issue of international harmonization with respect to the recommended alfalfa, timothy, and egg tolerances since there are no established international tolerances for these commodities. The tolerance for livestock meat byproducts is not harmonized with Codex as the potential hexythiazox residue level in meat byproducts may exceed the current Codex MRL.

C. Revisions to Petitioned-for Tolerances

Based on EPA's review of the data supporting the petition, Gowan Company revised their petition (PP 1F7934) as follows:

i. By increasing the proposed tolerances for alfalfa, forage to 15 ppm; alfalfa, hay to 30 ppm; timothy forage to 40 ppm; and timothy, hay to 40 ppm;

ii. By deleting the proposed tolerances for wheat, forage; wheat, hay; wheat, grain; and wheat, straw;

iii. By adding a request for an increase in the established tolerances for cattle, fat; goat, fat; horse fat; sheep fat; and milk to 0.05 ppm;

iv. By adding a request for an increase in the established tolerances for cattle meat byproducts; goat, meat byproducts; horse, meat byproducts; and sheep, meat byproducts to 0.20 ppm; and

v. By proposing tolerances for poultry, fat; and poultry, meat byproducts at 0.05 ppm; and egg at 0.01 ppm.

The Agency concluded that based on the residue data, these changes are required to support the new uses. The increase in the alfalfa and timothy tolerances were recommended by the Agency as a result of analyzing the submitted field trial data for these commodities using the OEDC MRL (Maximum Residue Limit) calculator. The increase in the livestock tolerances in fat and meat byproducts of ruminants are required due to the increased livestock dietary burden expected with the new uses on alfalfa and timothy. The increase in the ruminant fat and milk tolerances are recommended in order to account for the increased dietary burden to livestock and to be harmonized with Codex. Additionally, because of the potential increase of hexythiazox in the poultry diet, largely due to alfalfa use, and based on updated maximum reasonably balanced diet (MRBD) calculations for poultry, tolerances for eggs, poultry fat, and meat byproducts are required.

V. Conclusion

Therefore, tolerances are established for residues of hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety, as requested in the revised petition.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S.

Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 4, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.448 is amended as follows:

■ i. In paragraph (a), in the table, revise the entries for ''cattle, fat;'' ''cattle, meat byproducts;'' ''goat, fat;'' ''goat, meat byproducts;'' ''horse, fat;'' ''horse, meat byproducts;'' ''sheep, fat;'' ''sheep, meat byproducts;'' and ''milk.''

■ ii. In paragraph (a), in the table, add entries for ''poultry, fat;'' ''poultry, meat byproducts;'' and ''egg.''

■ iii. In paragraph (c), in the table, add entries for ''alfalfa, forage (EPA Regions 9–11 only;'' ''alfalfa, hay (EPA Regions 9–11 only;'' ''timothy, forage (EPA Regions 9–11 only;'' and ''timothy, hay (EPA Regions 9–11 only.''

The additions and revisions read as follows:

§ 180.448 Hexythiazox; tolerance for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Cattle, fat	0.05
Cattle, meat byproducts	0.20
* * * * *	
Egg	0.01
* * * * *	
Goat, fat	0.05
Goat, meat byproducts	0.20
* * * * *	
Horse, fat	0.05
Horse, meat byproducts	0.20
* * * * *	
Milk	0.05
* * * * *	
Poultry, fat	0.05
Poultry, meat byproducts	0.05
* * * * *	
Sheep, fat	0.05
Sheep, meat byproducts	0.20

* * * * *

(c) * * *

Commodity	Parts per million
Alfalfa, forage (EPA Regions 9–11 only)	15
Alfalfa, hay (EPA Regions 9–11 only)	30
* * * * *	
Timothy, forage (EPA Regions 9–11 only)	40
Timothy, hay (EPA Regions 9–11 only)	40

* * * * *

[FR Doc. 2013–02924 Filed 2–7–13; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

RIN 0648–XC453

Hawaii Crustacean Fisheries; 2013 Northwestern Hawaiian Islands Lobster Harvest Guideline

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notification of lobster harvest guideline.

SUMMARY: NMFS establishes the annual harvest guideline for the commercial lobster fishery in the Northwestern Hawaiian Islands (NWHI) for calendar year 2013 at zero lobsters.

DATES: February 8, 2013.

FOR FURTHER INFORMATION CONTACT: Jarad Makaiau, NMFS Pacific Islands Region, 808–944–2108.

SUPPLEMENTARY INFORMATION: The NWHI commercial lobster fishery is managed under the Fishery Ecosystem Plan for the Hawaiian Archipelago. The regulations at 50 CFR 665.252(b) require NMFS to publish an annual harvest guideline for lobster Permit Area 1, comprised of Federal waters around the (NWHI). Regulations governing the Papahanaumokuakea Marine National Monument in the NWHI prohibit the unpermitted removal of monument resources (50 CFR 404.7), and establish a zero annual harvest guideline for lobsters (50 CFR 404.10(a)). Accordingly, NMFS establishes the harvest guideline for the NWHI commercial lobster fishery for calendar year 2013 at zero lobsters. Thus, no harvest of NWHI lobster resources is allowed.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: February 5, 2013.

Kara Meckley,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2013–02887 Filed 2–7–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 111213751–2102–02]

RIN 0648–XC481

Fisheries of the Exclusive Economic Zone Off Alaska; Reallocation of Pacific Cod in the Bering Sea and Aleutian Islands Management Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; reallocation.

SUMMARY: NMFS is reallocating the projected unused amount of Pacific cod from vessels using jig gear to catcher vessels less than 60 feet (18.3 meters) length overall using hook-and-line or pot gear in the Bering Sea and Aleutian Islands management area. This action is necessary to allow the A season apportionment of the 2013 total allowable catch of Pacific cod to be harvested.

DATES: Effective February 5, 2013, through 2400 hours, Alaska local time (A.l.t.), December 31, 2013.

FOR FURTHER INFORMATION CONTACT: Obren Davis, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the Bering Sea and Aleutian Islands (BSAI) according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management

Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The A season apportionment of the 2013 Pacific cod total allowable catch (TAC) specified for vessels using jig gear in the BSAI is 1,950 metric tons (mt) as established by the final 2012 and 2013 harvest specifications for groundfish in the BSAI (77 FR 10669, February 23, 2012) and inseason adjustment (78 FR 270, January 3, 2013).

The Administrator, Alaska Region, NMFS, (Regional Administrator) has determined that jig vessels will not be able to harvest 1,800 mt of the A season apportionment of the 2013 Pacific cod TAC allocated to those vessels under § 679.20(a)(7)(ii)(A)(*1*). Therefore, in accordance with § 679.20(a)(7)(iv)(C), NMFS apportions 1,800 mt of Pacific cod from the A season jig gear apportionment to the annual amount specified for catcher vessels less than 60 feet (18.3 meters(m)) length overall (LOA) using hook-and-line or pot gear.

The harvest specifications for Pacific cod included in the final 2013 harvest specifications for groundfish in the BSAI (77 FR 10669, February 23, 2012) and inseason adjustment (78 FR 270, January 3, 2013) are revised as follows: 150 mt to the A season apportionment and 1,451 mt to the annual amount for vessels using jig gear, and 6,427 mt to catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the reallocation of Pacific cod specified from jig vessels to catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear. Since the fishery is currently open, it is important to immediately inform the industry as to the revised allocations. Immediate notification is necessary to allow for the orderly conduct and efficient operation of this fishery, to allow the industry to plan for the fishing season, and to avoid potential disruption to the fishing fleet as well as processors. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of February 4, 2013.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: February 5, 2013.

Kara Meckley,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2013–02885 Filed 2–5–13; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 111213751–2102–02]

RIN 6048–XC487

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Catcher Vessels Less Than 60 Feet (18.3 Meters) Length Overall Using Hook-and-Line or Pot Gear in the Bering Sea and Aleutian Islands Management Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by catcher vessels less than 60 feet (18.3 meters (m)) length overall (LOA) using hook-and-line or pot gear in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the 2013 Pacific cod total allowable catch (TAC) specified for catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear in the BSAI.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), February 7, 2013, through 2400 hours, A.l.t., December 31, 2013.

FOR FURTHER INFORMATION CONTACT: Obren Davis, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2013 Pacific cod TAC allocated as a directed fishing allowance to catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear in the BSAI is 6,427 metric tons as established by the final 2012 and 2013 harvest specifications for groundfish in the BSAI (77 FR 10669, February 23, 2012), inseason adjustment (78 FR 270, January 3, 2013), and one reallocation from the jig vessel sector (publication in the **Federal Register** pending).

In accordance with § 679.20(d)(1)(iii), the Administrator, Alaska Region, NMFS, has determined that the 2013 Pacific cod TAC allocated as a directed fishing allowance to catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear in the BSAI has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear in the BSAI.

After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of Pacific cod by catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear in the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of February 4, 2013.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of

prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: February 5, 2013.

Kara Meckley,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2013–02883 Filed 2–5–13; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 78, No. 27
Friday, February 8, 2013

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 27

[Doc. #AMS–CN–12–0024]

RIN 0581–AD26

Revision of Regulations Defining Bona Fide Cotton Spot Markets

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Agricultural Marketing Service (AMS) is proposing to amend the regulation that specifies which states compose bona fide cotton spot markets in order to assure consistency with the revised Cotton Research and Promotion Act. Updated bona fide spot market definitions will allow for published spot quotes to consider spot prices of cotton marketed in Kansas and Virginia. AMS is also proposing to amend references to the ''New York Cotton Exchange'' to read the ''Intercontinental Exchange.''

DATES: Comments must be received on or before March 11, 2013.

ADDRESSES: Interested persons may comment on the proposed rule using the following procedures:

- *Internet: http://www.regulations.gov.*
- *Mail:* Comments may be submitted by mail to: Darryl Earnest, Deputy Administrator, Cotton & Tobacco Programs, AMS, USDA, 3275 Appling Road, Room 11, Memphis, TN 38133. Comments should be submitted in triplicate. All comments should reference the docket number and the date and the page of this issue of the **Federal Register**. All comments will be available for public inspection during regular business hours at Cotton & Tobacco Program, AMS, USDA, 3275 Appling Road, Memphis, TN 38133. A copy of this notice may be found at: *www.ams.usda.gov/cotton/rulemaking.htm.*

FOR FURTHER INFORMATION CONTACT: Darryl Earnest, Deputy Administrator, Cotton & Tobacco Programs, AMS, USDA, 3275 Appling Road, Room 11, Memphis, TN 38133. Telephone (901) 384–3060, facsimile (901) 384–3021, or email *darryl.earnest@ams.usda.gov.*

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This proposed rule has been determined to be not significant for purposes of Executive Order 12866; and, therefore has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. There are no administrative procedures that must be exhausted prior to any judicial challenge to the provisions of this rule.

Regulatory Flexibility Act

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS has considered the economic impact of this action on small entities and has determined that its implementation will not have a significant economic impact on a substantial number of small businesses.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions so that small businesses will not be disproportionately burdened. There are an estimated 25,000 cotton growers in the U.S. who voluntarily use the AMS cotton classing services annually, and the majority of these cotton growers are small businesses under the criteria established by the Small Business Administration (13 CFR 121.201). Revisions to the regulations concerning bona fide spot market definitions are necessary to assure consistency with the revised Cotton Research and Promotion Act and to allow for published spot quotes to consider spot prices of cotton marketed in Kansas and Virginia. Changes in spot market definitions as stated will not significantly affect small businesses as defined in the RFA because:

(1) How spot prices are estimated are not expected to be impacted by this action;

(2) Business practices of the U.S. cotton industry are not expected to change as a result of this action;

(3) Costs associated with providing market news services will not be significantly changed by this action;

(4) Market news services are paid for by appropriated funds, therefore users are not charged fees for the provision of the services.

Paperwork Reduction Act

In compliance with OMB regulations (5 CFR part 1320), which implement the Paperwork Reduction Act (PRA) (44 U.S.C. 3501), the information collection requirements contained in the provisions to be amended by this proposed rule have been previously approved by OMB and were assigned OMB control number 0581–0009, Cotton Classification and Market New Service.

Background

The Secretary of Agriculture is authorized under the United States Cotton Futures Act (7 U.S.C. 15b) to designate at least five bona fide spot markets from which cotton price information can be collected. A spot market—also called the ''cash market'' or ''physical market''—is a market where commodities are sold on the spot for cash at current market prices and delivered immediately. Designation of these bona fide spot markets and the determination of which counties and states compose each of these spot markets was most recently published in the **Federal Register** on August 4, 1988 (53 FR 29327). For each of these bona fide spot markets, the Cotton and Tobacco Programs of the Agricultural Marketing Service collects market price information under the United States Cotton Futures Act (7 U.S.C. 15b), the Cotton Statistics and Estimates Act (7 U.S.C. 473b) and the Agricultural Marketing Act of 1946 (7 U.S.C. 1622(g)). This price information is then used to calculate price differences for cotton futures contracts.

The Food, Conservation, and Energy Act of 2008 (Pub. L. 110–234, 122 Stat. 923, enacted May 22, 2008, H.R. 2419) amended Section 17(f) of the Cotton Research and Promotion Act (7 U.S.C. 2116(f)), designating Kansas, Virginia, and Florida as cotton producing states for purposes of the Cotton Research and Promotion Act. To achieve consistency with the revised Cotton Research and Promotion Act and to allow for

published spot quotes to consider spot prices of cotton marketed in the aforementioned states, § 27.93 would be amended to add all the counties of Virginia to the Southeastern spot market, and Kansas to the East Texas and Oklahoma spot market.

On September 14, 2006, New York Board of Trade—the parent company of the New York Cotton Exchange—agreed to become a unit of Intercontinental Exchange. This transaction was completed on January 12, 2007. To reflect this organizational change in the regulations, § 27.94 would amend references to the ''New York Cotton Exchange'' to read as the ''Intercontinental Exchange.''

List of Subjects in 7 CFR Part 27

Commodity futures, Cotton.

For the reasons set forth in the preamble, 7 CFR part 27 is proposed to be amended as follows:

PART 27—[Amended]

■ 1. The authority citation for 7 CFR part 27 continues to read as follows:

Authority: 7 U.S.C. 15b, 7 U.S.C. 473b, 7 U.S.C. 1622(g).

■ 2. In § 27.93, definitions of the Southeastern market and the East Texas and Oklahoma market are revised to read as follows:

§ 27.93 Bona fide spot markets.

* * * * *

Southeastern

All counties in the states of Alabama, Florida, Georgia, North Carolina, South Carolina, and Virginia and all counties in the state of Tennessee east of and including Stewart, Houston, Humphreys, Perry, Wayne and Hardin counties.

* * * * *

East Texas and Oklahoma

All counties in the states of Kansas and Oklahoma and the Texas counties east of and including Montague, Wise, Parker, Erath, Comanche, Mills, San Saba, Mason, Sutton, Edwards, Kinney, Maverick, Webb, Zapata, Star and Hidalgo counties.

* * * * *

■ 3. In § 27.94, paragraph (a) is revised to read as follows:

§ 27.94 Spot markets for contract settlement purposes.

* * * * *

(a) For cotton delivered in settlement of any No. 2 contract on the Intercontinental Exchange (ICE); Southeastern, North and South Delta, Eastern Texas and Oklahoma, West Texas, and Desert Southwest.

* * * * *

Dated: February 4, 2013.

David R. Shipman,

Administrator, Agricultural Marketing Service.

[FR Doc. 2013–02811 Filed 2–7–13; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 920

[Doc. No. AMS–FV–12–0008; FV12–920–1 PR]

Kiwifruit Grown in California; Proposed Amendments to Marketing Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This rule invites comments on five proposed amendments to Marketing Order No. 920 (order) which regulates the handling of kiwifruit grown in California. The amendments were proposed by the Kiwifruit Administrative Committee (Committee or KAC), which is responsible for local administration of the order. The five proposals would amend the marketing order by adding authority to recommend and conduct production and postharvest research, adding authority to recommend and conduct market research and development projects, adding authority to receive and expend voluntary contributions, amending procedures to specify that recommendations for production research and market development be approved by eight members of the Committee, and updating provisions regarding alternate members' service on the Committee.

DATES: Comments must be received by April 9, 2013.

ADDRESSES: Written comments should be submitted to the Docket Clerk, Marketing Order and Agreement Division, Fruit and Vegetable Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or Internet: *http://www.regulations.gov.* All comments should reference the document number and the date and page number of this issue of the **Federal Register**. All comments submitted in response to this proposed rule will be included in the record and will be made available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http://www.regulations.gov.* Please be advised that the identity of the individuals or entities submitting the comments will be made public on the Internet at the address provided above.

To the extent practicable, all documents filed with the Docket Clerk should also be submitted electronically to Kathleen Bright at the email address noted for her in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Kathleen Bright, Marketing Order and Agreement Division, Fruit and Vegetable Program, AMS, USDA; 1400 Independence Avenue SW., Stop 0237, Washington, DC 20250–0237; Telephone: (202) 205–2830, Fax: (202) 720–8938 or Email: *Kathleen.Bright@ams.usda.gov.*

Small businesses may request information on complying with this regulation by contacting Laurel May, Marketing Order and Agreement Division, Fruit and Vegetable Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Laurel.May@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This proposal is issued under Marketing Order No. 920, as amended (7 CFR part 920), regulating the handling of kiwifruit produced in California, hereinafter referred to as the ''order.'' The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' Section 608c(17) of the Act and the applicable rules of practice and procedure governing the formulation of marketing agreements and orders (7 CFR part 900) authorize amendment of the order through this informal rulemaking action. AMS will consider comments received in response to this rule, and based on all the information received, will determine if order amendment is warranted. If AMS determines amendment of the order is warranted, a subsequent proposed rule and referendum order would be issued and producers would be allowed to vote for or against the proposed order amendments. AMS would then issue a final rule effectuating any amendments approved by producers in the referendum.

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Order 12866.

This proposal has been reviewed under Executive Order 12988, Civil

Justice Reform. This rule is not intended to have retroactive effect. This rule shall not be deemed to preclude, preempt, or supersede any research and market development provisions of any State program covering California kiwifruit.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

Section 1504 of the Food, Conservation, and Energy Act of 2008 (2008 Farm Bill) (Pub. L. 110–246) amended section 18c(17) of the Act, which in turn required the addition of supplemental rules of practice to 7 CFR part 900 (73 FR 49307; August, 21, 2008). The amendment of section 18c(17) of the Act and additional supplemental rules of practice authorize the use of informal rulemaking (5 U.S.C. 553) to amend federal fruit, vegetable, and nut marketing agreements and orders. USDA may use informal rulemaking to amend marketing orders based on the nature and complexity of the proposed amendments, the potential regulatory and economic impacts on affected entities, and any other relevant matters.

AMS has considered these factors and has determined that the amendment proposals are not unduly complex and the nature of the proposed amendments is appropriate for utilizing the informal rulemaking process to amend the order. A discussion of the potential regulatory and economic impacts on affected entities is discussed later in the ''Initial Regulatory Flexibility Analysis'' section of this rule. AMS will analyze any comments received on the amendments proposed in this rule. If it determines to proceed with this amendatory action based on an analysis of the comments and all other available information, it will conduct a producer referendum to determine grower support for the proposed amendments. Any proposed amendments approved by producers in referendum would be effectuated through issuance of a final rule.

The proposed amendments were unanimously recommended by the Committee following deliberations at public meetings on July 12 and December 13, 2011. The Committee's proposed amendments would amend the marketing order by: (1) Adding authority to recommend and conduct production and postharvest research, (2) adding authority to recommend and conduct market research and development projects, (3) adding authority to receive and expend voluntary contributions, (4) amending procedures to specify that recommendations for production research and market development be approved by eight members of the Committee, and (5) clarifying provisions regarding alternate members' service on the Committee.

In addition to these proposed amendments, AMS proposes to make any additional changes to the order as may be necessary to conform to any amendment that may result from this rulemaking action.

Proposal Number 1—Production and Postharvest Research

This proposal would add section 920.47 to authorize production and postharvest research to assist or improve the efficient production and postharvest handling of kiwifruit. Adding this authority would provide the Committee with the ability to conduct production research, food quality and handling research, and to distribute that information. These functions were previously conducted by the California Kiwifruit Commission (CKC), a State of California program which ceased to exist on September 30, 2011.

Kiwifruit is a relatively new crop to California with the first commercial crop produced in 1971. The CKC was established in 1979, five years prior to the kiwifruit marketing order. The CKC performed marketing research and development programs for the industry. When the kiwifruit marketing order was established in 1984, its main purpose was to implement quality and pack and container regulations. The two programs worked independently, and the industry chose not to add authority for production and postharvest research to the Federal order at inception to avoid duplication. According to the Committee, industry leaders believed that having programs serving separate and distinct functions would best serve the interests of the kiwifruit industry.

Over the past two decades, California kiwifruit acreage and the number of growers have decreased, from a peak in 1992 of 7,300 producing acres and 690 producers to 4,200 producing acres and 175 growers today, according to data from the National Agricultural Statistics Service and the Committee. As a result, the industry has cut back programs supported by industry assessments. In the early 2000s, industry leaders began to evaluate industry programs in an effort to determine which ones were the most beneficial and actively sought ways to make the administration of these programs more cost efficient and effective. The need for production and postharvest research is repeatedly identified as one of the most important programs to the industry, along with market development programs. According to the Committee, there is a general consensus throughout the industry that the future administration of these activities should be done through one program and because there is widespread support to maintain the quality and pack and container requirements, that program should be the Federal marketing order.

The Committee believes that for the California kiwifruit industry to remain productive and competitive, management practices must continue to evolve. It further believes that production and postharvest research was one of the most beneficial activities performed by the CKC. Over the years, these activities helped growers become knowledgeable on how to establish vineyards, prune, thin, irrigate, pollinate, fertilize, manage diseases, harvest, store and transport kiwifruit. According to the Committee, the industry wants the KAC to conduct these activities since the CKC no longer exists.

The Committee believes production and postharvest research would have a direct and positive impact on producers, handlers, and consumers. Diseases, such as the infectious vine-killing bacterial disease known as PSA, confirmed in New Zealand in 2010, decimated 28% of New Zealand orchards. With no current organization equipped to facilitate research activities, the same could happen to California kiwifruit. Production research could help develop cultural practices to reduce the likelihood of a similar incident in the United States. In addition, food quality and handling practices are important issues to producers, handlers, and consumers. The industry desires to take a proactive stance to be prepared to address any challenges in this area.

Also, with no research organization, the Committee is unable to participate in the joint global research effort with the International Kiwifruit Organization (IKO). The IKO jointly funds research

activities with other organizations that benefit kiwifruit producers and consumers on a global basis. Approval of this proposal would ensure the industry's continued ability to participate in these activities.

Adding production research to the order is expected to improve returns for producers because it will enable the industry to develop new technologies to increase yields, improve fruit quality and production, and facilitate postharvest research.

There is a potential cost of increased assessments to fund projects. However, the KAC would evaluate the costs against the potential benefits. The USDA would review and approve activities prior to their undertaking. In addition, the KAC would evaluate activities after they are completed to ensure that goals and objectives are met.

For the reasons stated above, it is proposed that section 920.47 be added to authorize production and postharvest research to assist or improve the efficient production and postharvest handling of kiwifruit.

Proposal Number 2—Market Research and Development

This proposal would add section 920.48 to authorize marketing research and development programs to promote, assist, or improve the marketing, distribution, and consumption of kiwifruit. Adding this authority would enable the industry to continue to conduct these activities that were previously conducted by the CKC.

The California kiwifruit industry, as a whole, has undergone many changes since the inception of the marketing order in 1984. The industry experienced significant growth in the 1980s, but acreage and production levels have since declined. According to the Committee, this has caused industry leaders to evaluate which programs are most beneficial to the industry and the most efficient way to conduct such programs. Through an industry vote, the CKC was discontinued in 2011, as previously discussed. The Committee believes that marketing research and development activities previously conducted by the CKC are beneficial to the industry but can be conducted under the Federal marketing order. This creates efficiencies by using one industry organization to carry out the functions previously conducted by two organizations. Therefore, the Committee supports maintaining the Federal marketing order and adding marketing research and development authority to the order.

Providing authority for the Committee to conduct marketing research and development programs would assist the industry with marketing, distribution, and consumption of kiwifruit. The Committee could undertake marketing, research, and development activities such as conducting market and consumer surveys, which could identify consumer and market preferences. Further, adding this authority to the marketing order would enable the Committee to apply for Market Access Program (MAP) funds from the USDA and engage in jointly funded export marketing research and development activities. Participation in jointly funded programs and MAP funds was identified as a priority by the Committee in its strategic planning in the early 2000s. These types of activities would be designed to increase the demand and sales of California kiwifruit, with the intent of increasing returns to producers.

There is a potential cost of increased assessments to fund projects. However, the KAC would evaluate the costs against the potential benefits. The USDA would review and approve activities prior to their undertaking. The KAC would evaluate activities after they are completed to ensure that goals and objectives are met. In addition, the Federal Agricultural Improvement and Reform Act of 1996 (1996 Farm Bill) (Pub. L. 104–127) requires Federal marketing order promotion activities to be evaluated by an independent party to ensure they are effective. Thus, any such programs conducted under the order would be evaluated to ensure the benefits exceed the costs.

For the reasons stated above, it is proposed that section 920.48 be added to authorize marketing research and development programs to promote, assist, or improve the marketing, distribution and consumption of kiwifruit.

Proposal Number 3—Voluntary Contributions

This proposal would add section 920.45 to authorize the Committee to receive and expend voluntary contributions for market development projects, market research, and production and postharvest research. The proposal also contains a provision that any voluntary contributions would be free from any encumbrances by the donor and the Committee would retain complete control of their use. Currently, the Committee only has authority to collect and spend assessment dollars. In the event that proposal number one and/or proposal number two are adopted, for example, the ability to accept voluntary contributions would provide the Committee with additional funding sources for production and postharvest research, and marketing research and development activities.

This proposal compliments and supports proposal numbers one and two. If adopted, this proposal could help provide financial support for marketing research and development activities. Producers and handlers could benefit from these activities as discussed under proposal numbers one and two. Examples of additional funding sources include voluntary donations and non-industry sources such as grants. If the Committee received funding from these additional sources, it could help to mitigate potential assessment rate increases to fund research and development projects.

The Committee would clearly communicate that voluntary contributions accepted would be free from any encumbrances by the donor and the Committee would retain control over the use of the funds.

For the reasons stated above, it is proposed that section 920.45 be added to authorize the Committee to receive and expend voluntary contributions for market development projects, market research, and production and postharvest research.

Proposal Number 4—Committee Quorum

This proposal would modify section 920.32 so that approval by eight members of the Committee is required for market research and development as well as production and postharvest research activities. The proposed change to require an eight vote majority on marketing research and development issues is consistent with industry practices and voting requirements for Committee actions on other issues. The Committee is comprised of twelve members and alternates. This proposal will help to ensure industry support exists before undertaking these activities.

Section 920.32 of the order provides that actions of the Committee require a majority vote, except that eight concurring votes are required by the Committee with respect to actions concerning expenses, assessments, or recommendations for regulations. The addition of approval by eight members for marketing research and development activities would be consistent with current Committee procedures regarding issues of major importance to the industry. Requiring eight concurring votes would ensure that major actions of the Committee would have a super majority, indicating that a broad level of industry support exists prior to

undertaking marketing research and development activities.

For the reasons stated above, it is proposed that section 920.32 be modified so that approval by eight members of the Committee is required for market research and development as well as production and postharvest research activities.

Proposal Number 5—Alternate Member Procedures

This proposal would modify section 920.27 to update and clarify procedures for substitute alternates from within the same district to represent absent members at Committee meetings in districts with more than two members. Further, this proposal would clarify existing language in the order by providing the authority for substitute alternates within the same district to represent absent members. This is a necessary change designed to update existing language.

Prior to 2010, the production area covered by the order was comprised of eight districts, represented by one or two members, and an alternate member for each district, for a total of twenty-two grower positions. In 2010, the order was amended and the number of districts decreased to three. Each district is now represented on the Committee by two, four or five members and alternate members, for a total of twenty-two grower positions. However, section 920.27 only addresses alternate members' service on the Committee in districts with one and two grower positions. This proposal addresses alternate members' service on the Committee in districts with more than two members, as well as, alternates if both a member and his or her respective alternate are unable to attend a Committee meeting. In such situations, the Committee would be authorized to designate any other alternate present, in the same district, to serve in place of the absent member.

Updating the order to clarify procedures for substitute alternates' service on the Committee would help to ensure that quorum requirements are met. It would also contribute to an orderly flow of Committee business resulting in a positive impact on producers, handlers, and consumers.

For the reasons stated above, it is proposed that section 920.27 be modified to update and clarify procedures for substitute alternates from within the same district, to represent absent members at Committee meetings in districts with more than two members.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

Based on committee data, there are approximately 175 producers and 27 handlers of kiwifruit in the California production area. The Small Business Administration (SBA) defines small agricultural producers as those having annual receipts of less than $750,000, and small agricultural service firms are defined as those having annual receipts of less than $7,000,000. (13 CFR 121.201).

The California Agricultural Statistical Service (CASS) reported total California kiwifruit production for the 2010–11 season at 32,700 tons, with an average price of $768 per ton. Based on the average price, shipment, and grower information provided by the CASS and the Committee, it could be concluded that the majority of kiwifruit handlers would be considered small businesses under the SBA definition. In addition, based on kiwifruit production and price information, as well as the total number of California kiwifruit growers, the average annual grower revenue is less than $750,000. Thus, the majority of California kiwifruit producers may also be classified as small entities.

The amendments proposed by the Committee would provide authority to recommend and conduct production and postharvest research, add authority to recommend and conduct marketing research and development projects, add authority to receive and expend voluntary contributions, amend procedures to specify that recommendations for production research and market development be approved by eight members of the Committee, and update provisions regarding alternate members' service on the Committee.

These proposed amendments were unanimously recommended at public meetings of the Committee held on July 12 and December 13, 2011.

If proposal number one regarding adding research authority to the order is approved in referendum, there would be no immediate costs to growers or handlers. This proposal would only provide authority to recommend production and postharvest research activities. In the event, the Committee decided to undertake these activities in the future, there would be a cost associated with funding any projects recommended. However, research activities were previously funded by the industry through the CKC, which no longer exists. Therefore, there would be no net increase in costs to the industry; the costs would merely be shifted from one industry organization to another.

Section 920.41(b) of the order establishes a maximum limit on the assessment rate that may be implemented. The limit was established at $.035 per tray equivalent (6.8 pounds) when the order was promulgated in 1984, and may be adjusted for inflation. The assessment rate currently in effect is $.035 per 19.8-pound (9 kilo) container, or approximately $.012 per tray equivalent (§ 920.213). The current rate is well below the maximum authorized under the order and any potential increase in the assessment rate to cover the costs of research activities is anticipated to be well within the maximum assessment rate authorized under the order. Therefore, the Committee did not recommend an increase in the assessment rate limitation. In addition, if proposal number three, regarding authority for the Committee to accept voluntary contributions is approved, it could provide additional sources of revenue and reduce the amount of assessment monies otherwise needed to fund research activities.

Although there would be a cost associated with any research activities undertaken by the industry, the benefits of such activities would be expected to outweigh the costs. Past benefits of production research to the California kiwifruit industry include improved techniques for establishing vineyards, improved techniques for pruning, thinning, irrigating, pollination, fertilizer application, disease and pest management, and harvesting. Benefits of postharvest research include improved methods of fruit storage, packaging, and transportation. These research results have been disseminated to growers and handlers in the past and have been instrumental in maintaining a viable kiwifruit industry in California. The Committee believes a continuation of these types of activities is important to the long term success of the industry.

Prior to undertaking any research activities, the Committee would evaluate potential projects and their costs against the potential benefits to the industry. Any projects recommended by the Committee would be reviewed and approved by USDA before being implemented. The Committee and USDA would provide oversight to help ensure that the goals and objectives were being met. The results would be disseminated to industry members and would also be available to the public.

If proposal number two regarding adding authority to the order for marketing research and development projects is approved, there would be no immediate costs to the industry, as with proposal number one. This proposal would similarly only provide authority to recommend production and postharvest research activities. In the event, the Committee decided to undertake these activities in the future, there would be a cost associated with funding any marketing research and development projects recommended. These activities were also previously funded by the CKC, so any costs associated with undertaking them would likewise be shifted from one kiwifruit industry organization to another, and there may not be an overall cost increase to the industry, as a whole.

Like production and postharvest research activities discussed above, marketing research and development projects could also receive supplemental funding through receipt of voluntary contributions if proposal number three is approved. This could help to mitigate any possible assessment rate increases to pay for the costs of these activities. To the extent that the assessment rate may need to be increased, any increase would be limited so it remains within the maximum level authorized under section 920.41 of the order.

Any increased costs associated with marketing research and development activities are expected to be outweighed by the benefits. Marketing research could be conducted regarding consumers' tastes and preferences, and this type of information is valuable in developing marketing strategies. Collection of market data can also be useful to determine the success of prior programs and to develop future programs. Market development programs could be used to conduct programs designed to increase awareness and demand for California kiwifruit. These demand building activities would be expected to increase sales with the intent of ultimately increasing returns to producers.

Prior to undertaking any marketing research and/or market development activities, the Committee would evaluate potential projects and their costs against the potential benefits to the industry. Any projects recommended by the Committee would be reviewed and approved by USDA before being implemented. The Committee would provide oversight to ensure the goals and objectives were being met. In addition, as required by the Federal Agricultural Improvement and Reform Act of 1996, any marketing research and development programs engaged in under a Federal marketing order require periodic evaluation by an independent third party to ensure they are effective. Thus, any such programs conducted under the kiwifruit order would be evaluated to help ensure the benefits exceed the costs.

Proposal number three would provide authority for the Committee to receive voluntary contributions to help fund marketing research and development activities. If approved and utilized, this could provide an additional source of revenue to help supplement the funding of research and development programs. These types of programs are intended to benefit the entire industry. This proposal would not increase or decrease any reporting, record keeping, or compliance costs. Acceptance of voluntary financial contributions by the Committee would not result in increased costs. Rather, it might reduce the amount of assessment revenue needed to fund a given program or programs.

Proposal numbers four and five relate to voting procedures and alternate members' service on the Committee. Both are procedural in nature and would have no economic impact on producers or handlers if they are approved because they would not establish any regulatory requirements on handlers, nor do they contain any assessment or funding implications. There would be no change in financial costs, reporting, or recordkeeping requirements if either of these proposals is approved.

Alternatives to these proposals, including making no changes at this time, were considered. However, the Committee believes it would be beneficial to have the means necessary to conduct production research and market development, as well as collecting voluntary contributions, and clarifying procedural language for Committee meetings.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the order's information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0189, Generic OMB Fruit Crops. No changes in those requirements as a result of this proceeding are anticipated. Should any changes become necessary, they would be submitted to OMB for approval.

As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

In addition, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

The Committee's meetings, at which these proposals were discussed, were widely publicized throughout the kiwifruit industry. All interested persons were invited to attend the meeting and encouraged to participate in Committee deliberations on all issues. Like all Committee meetings, the meeting was public, and all entities, both large and small, were encouraged to express their views on these proposals.

Finally, interested persons are invited to submit comments on the proposed amendments to the order, including comments on the regulatory and informational impacts of this action on small businesses. Following analysis of any comments received on the amendments proposed in this rule, AMS will evaluate all available information and determine whether to proceed. If so, a proposed rule and referendum order would be issued and producers would be provided the opportunity to vote for or against the proposed amendments. Information about the referendum, including dates and voter eligibility requirements, would be published in a future issue of the **Federal Register**. A final rule would then be issued to effectuate any amendments favored by producers participating in the referendum.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *www.ams.usda.gov/MarketingOrdersSmallBusinessGuide.* Any questions about the compliance guide should be sent to Laurel May at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

General Findings

The findings hereinafter set forth are supplementary to the findings and determinations which were previously made in connection with the issuance of the marketing order; and all said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

1. The marketing order, as amended, and as hereby proposed to be further amended, and all of the terms and conditions thereof, would tend to effectuate the declared policy of the Act;

2. The marketing order, as amended, and as hereby proposed to be further amended, regulates the handling of kiwifruit grown in California in the same manner as, and is applicable only to, persons in the respective classes of commercial and industrial activity specified in the marketing order;

3. The marketing order, as amended, and as hereby proposed to be further amended, is limited in application to the smallest regional production area which is practicable, consistent with carrying out the declared policy of the Act, and the issuance of several orders applicable to subdivisions of the production area would not effectively carry out the declared policy of the Act;

4. The marketing order, as amended, and as hereby proposed to be further amended, prescribes, insofar as practicable, such different terms applicable to different parts of the production area as are necessary to give due recognition to the differences in the production and marketing of kiwifruit produced or packed in the production area; and

5. All handling of kiwifruit produced or packed in the production area as defined in the marketing order is in the current of interstate or foreign commerce or directly burdens, obstructs, or affects such commerce.

A 60-day comment period is provided to allow interested persons to respond to these proposals. Any comments received on the amendments proposed in this rule will be analyzed, and if AMS determines to proceed based on all the information presented, a producer referendum would be conducted to determine grower support for the proposed amendments. If appropriate, a final rule would then be issued to effectuate the amendments favored by producers participating in the referendum.

List of Subjects in 7 CFR Part 920

Kiwifruit, Marketing agreements, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 920 is proposed to be amended as follows:

PART 920—KIWIFRUIT GROWN IN CALIFORNIA

■ 1. The authority citation for 7 CFR part 920 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Revise § 920.27 to read as follows:

§ 920.27 Alternate members.

An alternate member of the committee, during the absence of the member for whom that individual is an alternate, shall act in the place and stead of such member and perform such other duties as assigned. In the event both a member and his or her alternate are unable to attend a committee meeting, the committee may designate any other alternate member from the same district to serve in such member's place and stead. In the event of the death, removal, resignation, or disqualification of a member, the alternate of such member shall act for him or her until a successor for such member is selected and has qualified.

■ 3. In § 920.32, revise paragraph (a) to read as follows:

§ 920.32 Procedure.

(a) Eight members of the committee, or alternates acting for members, shall constitute a quorum and any action of the committee shall require the concurring vote of the majority of those present: *Provided,* That actions of the committee with respect to expenses and assessments, production and postharvest research, market research and development, or recommendations for regulations pursuant to §§ 920.50 through 920.55, of this part shall require at least eight concurring votes.

* * * * *

■ 4. Add § 920.45 to read as follows:

§ 920.45 Contributions.

The committee may accept voluntary contributions, but these shall only be used to pay expenses incurred pursuant to §§ 920.47 and 920.48. Furthermore, such contributions shall be free from any encumbrances by the donor, and the committee shall retain complete control of their use.

■ 5. Add § 920.47 to read as follows:

§ 920.47 Production and postharvest research.

The committee, with the approval of the Secretary, may establish or provide for the establishment of projects involving research designed to assist or improve the efficient production and postharvest handling of kiwifruit.

■ 6. Add § 920.48 to read as follows:

§ 920.48 Market research and development.

The committee, with the approval of the Secretary, may establish or provide for the establishment of marketing research and development projects designed to assist, improve, or promote the marketing, distribution, and consumption of kiwifruit.

Dated: February 4, 2013.

David R. Shipman,

Administrator, Agricultural Marketing Service.

[FR Doc. 2013–02810 Filed 2–7–13; 8:45 am]

BILLING CODE 3410–02–P

FEDERAL HOUSING FINANCE AGENCY

12 CFR Part 1215

RIN 2590–AA51

Production of FHFA Records, Information, and Employee Testimony in Legal Proceedings

AGENCY: Federal Housing Finance Agency.

ACTION: Notice of proposed rulemaking; with request for comments.

SUMMARY: The Federal Housing Finance Agency (FHFA) proposes a regulation governing the production of FHFA records, information or employee testimony in connection with legal proceedings in which neither the United States, nor FHFA is a party. This proposed rule would establish requirements and procedures for demanding or requesting parties to submit demands or requests, and factors for FHFA to consider in determining whether FHFA employees will provide records, information or testimony relating to their official duties. FHFA's desirable intent is to standardize practices, promote uniformity in decisions, preserve the ability of FHFA to conduct agency business, protect confidential information, provide guidance to demanding or requesting parties, minimize involvement in matters unrelated to the agency missions and programs of FHFA, avoid wasteful allocation of agency resources, and preclude spending public time and money for private purposes.

DATES: Comments on this proposed rule are due 60 days after publication. For additional information, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: You may submit your comments, identified by Regulatory Information Number (RIN) 2590–AA51, by any of the following methods:

- *Email:* Comments to Alfred M. Pollard, General Counsel, may be sent by email to *RegComments@fhfa.gov.* Please include Comments/RIN 2590–AA51 in the message's subject line.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. If you submit your comment to the *Federal eRulemaking Portal,* please also send it by email to FHFA at *RegComments@fhfa.gov* to ensure timely receipt by the Agency. Please include Comments/RIN 2590–AA51 in the subject line of the message.
- *Courier/Hand Delivery:* The hand delivery address is: Alfred M. Pollard, General Counsel, Attention: Comments/RIN 2590–AA51, Federal Housing Finance Agency, Constitution Center, Eighth Floor, 400 Seventh Street SW., Washington, DC 20024. The package should be logged in at the Guard's Desk, First Floor, on business days between 9 a.m. and 5 p.m.
- *U.S. Mail, United Parcel Service, Federal Express or Other Mail Service:* The mailing address for comments is: Alfred M. Pollard, General Counsel, Attention: Comments/RIN 2590–AA51, Federal Housing Finance Agency, Constitution Center, Eighth Floor, 400 Seventh Street SW., Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: James P. Jordan, Senior Counsel, 202–649–3075 (not a toll-free number), Federal Housing Finance Center, Constitution Center, Eighth Floor, 400 Seventh Street SW., Washington, DC 20024. The telephone number for the Telecommunications Device for the Hearing Impaired is 800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Comments

FHFA invites comments on all aspects of the proposed rule, and may revise the language of the proposed rule as appropriate after taking all comments into consideration. Copies of all comments received will be posted without change on the FHFA web site at *http://www.fhfa.gov,* and will include any personal information you provide, such as your name, address, email address, and telephone number. Copies of all comments received will be made available for examination by the public on business days between the hours of 10 a.m. and 3 p.m., at the Federal Housing Finance Agency, Constitution Center, Eighth Floor, 400 Seventh St. SW., Washington, DC 20024. To make an appointment to inspect comments, please call the Office of General Counsel at 202–649–3804

II. Background

A. Establishment of FHFA

The Housing and Economic Recovery Act of 2008 (''HERA''), Public Law No. 110–289, 122 Stat. 2654, amended the Federal Housing Enterprises Financial Safety and Soundness Act of 1992 (Safety and Soundness Act) (12 U.S.C. 4501 *et seq.*) and the Federal Home Loan Bank Act (12 U.S.C. 1421–1449) to establish FHFA as an independent agency of the Federal Government. HERA transferred the supervisory and oversight responsibilities of the Office of Federal Housing Enterprise Oversight over Fannie Mae and Freddie Mac, and of the Federal Housing Finance Board over the Federal Home Loan Banks and the Bank System's Office of Finance, to FHFA. FHFA is tasked with ensuring that the Federal National Mortgage Association, the Federal Home Loan Mortgage Corporation, and the Federal Home Loan Banks (collectively, the regulated entities) operate in a safe and sound manner; foster liquid, efficient, competitive and resilient national housing finance markets; comply with their respective authorizing statutes, and all rules, regulations, guidelines, and orders issued pursuant to those authorities; carry out their missions through duly authorized activities; and that their activities and operations are consistent with the public interest. Section 1105 of HERA amended the Safety and Soundness Act and the Inspector General Act of 1978 to establish an Inspector General within FHFA. *See* 12 U.S.C. 4517(d). Among other duties, FHFA Office of Inspector General (''FHFA–OIG'') is responsible for conducting audits, evaluations, and investigations of FHFA's programs and operations; recommending policies that promote economy and efficiency in the administration of FHFA's programs and operations; and preventing and detecting fraud, waste and abuse in FHFA's programs and operations.

B. Need for Proposed Rule

Federal agencies often receive formal demands (including subpoenas) or informal requests to produce records, information, or testimony in judicial, legislative or administrative proceedings in which those agencies or the United States is not a named party. Many federal agencies have issued regulations to address the submission, evaluation, and processing of these demands or requests. They have done so because responding to these demands or requests is burdensome, may disrupt an agency employee's work schedule significantly, may involve the agency in issues unrelated to its responsibilities, may divert agency resources from accomplishing mission critical functions, and may impede the agency's accomplishment of its mission and goals. Standard rules alleviate these difficulties by ensuring timely notice and centralized, objective decision making. The United States Supreme Court upheld this type of regulation in *United States ex rel. Touhy* v. *Ragen,* 340 U.S. 462 (1951), holding that provisions in the federal ''housekeeping'' statute, 5 U.S.C. 22, 5 U.S.C.A. 22 (now 5 U.S.C. 301), authorize agencies to promulgate rules governing record production and employee testimony.

Since the establishment of FHFA and the establishment of the FHFA–OIG within FHFA, FHFA has not issued a regulation governing the submission, evaluation, and processing of demands or requests in connection with a legal proceeding. This proposed rule fills that gap and replaces applicable legacy regulations issued by FHFA's predecessor agencies, the Office of Federal Housing Enterprise Oversight and the Federal Housing Finance Board. The proposed rule would prohibit FHFA employees from producing records, information, or testimony in response to demands or requests, unless the demands or requests comply with the rule, *and* FHFA then grants permission for the production. Compliance with the rule is necessary, but not sufficient, for production to occur. The proposed rule identifies the information that demanding or requesting parties must provide and the factors that FHFA may consider when evaluating demands or requests.

The proposed rule would ensure a more efficient use of agency resources, minimize the possibility of involving FHFA in issues unrelated to its mission, promote uniformity in responding to demands or requests, and maintain the impartiality of FHFA in matters that are in dispute between other parties. It will also serve the interests of FHFA in protecting sensitive, confidential and privileged information and records that are generated and compiled in the performance of official duties.

For these reasons, public notice and opportunity to comment are not required under the Administrative Procedure Act, but FHFA is providing such notice and opportunity to comment as a matter of discretion.

III. Section-by-Section Analysis

Section 1215.1 Scope and Purpose

This section describes the rule's scope, which includes internal agency operations. This section also sets forth the rule's purpose, which is to specify the manner in which, and standards by which, demands or requests for records, information, or testimony must be submitted, evaluated, and processed.

Section 1215.2 Applicability

This section identifies those demands or requests for FHFA records, information, or testimony that are subject to the rule. This section also states the types of demands or requests excepted from the rule.

Section 1215.3 Definitions

This section defines terms relevant to the regulation.

Section 1215.4 General Prohibition

This section bars producing FHFA records, information, or testimony in response to a demand or request without proper written authorization.

Section 1215.5 Delegation

This section authorizes FHFA's Director to delegate his authority under this part.

Section 1215.6 Factors FHFA May Consider

This section sets forth factors that FHFA may consider when evaluating demands or requests.

Section 1215.7 Serving Demands and Submitting Requests

This section describes the manner in which demands or requests for FHFA records, information, or testimony must be served and submitted.

Section 1215.8 Timing and Form of Demands and Requests

This section describes the timing by which and the form in which a demanding or requesting party must serve its demand or submit its request.

Section 1215.9 Failure To Meet This Part's Requirements

This section describes the consequences of failing to meet requirements set forth in this part.

Section 1215.10 Processing Demands and Requests

This section describes how demands or requests must be processed and establishes deadlines. This section also provides the limited instances in which these processes or deadlines may be waived.

Section 1215.11 FHFA Determination

This section authorizes FHFA's Director to make FHFA's determination on demands or requests for information to be provided by FHFA. This section also describes the notice to be provided to the demanding or requesting parties when an FHFA determination is made.

Section 1215.12 Restrictions That Apply to Testimony

This section authorizes the imposition of conditions on FHFA employee testimony.

Section 1215.13 Restrictions That Apply to Records and Information

This section authorizes the imposition of conditions on production of FHFA records or information.

Section 1215.14 Procedure in the Event of an Adverse FHFA Determination

This section establishes an administrative mechanism by which parties aggrieved by an FHFA determination about a demand or request may seek reconsideration of that determination. This section also establishes a petition for FHFA reconsideration as a prerequisite to judicial review.

Section 1215.15 Conflicting Court Order

This section directs persons in possession of FHFA information to decline to comply with a court order that conflicts with an FHFA determination.

Section 1215.16 Fees

This section describes FHFA's entitlement to fees arising from the production of requested records, information, or testimony.

IV. Paperwork Reduction Act

The proposed rule does not contain any information collection requirement that requires the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

V. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires that a regulation that has a significant economic impact on a substantial number of small entities, small businesses, or small organizations must include an initial regulatory flexibility analysis describing the regulation's impact on small entities. Such an analysis need not be undertaken if the agency has certified that the regulation will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605(b). FHFA has considered the impact of the regulation under the Regulatory Flexibility Act. FHFA certifies that the proposed regulation, if adopted, is not likely to have a significant economic impact on a substantial number of small business entities because the regulation is applicable only to the internal operations and legal obligations of FHFA and FHFA–OIG.

List of Subjects in 12 CFR Part 1215

Administrative practice and procedure, Courts, Government employees, Records, Subpoenas, Testimony.

For the reasons set forth in the **SUPPLEMENTARY INFORMATION**, and under the authority of 12 U.S.C. 4526, the Federal Housing Finance Agency proposes to amend Chapter XII of Title 12 of the Code of Federal Regulations by adding a new part 1215.

■ 1. Add Part 1215 to read as follows:

PART 1215—PRODUCTION OF FHFA RECORDS, INFORMATION, AND EMPLOYEE TESTIMONY IN LEGAL PROCEEDINGS

Sec.

Authority: 5 U.S.C. 301; 12 U.S.C. 4526.

§ 1215.1 Scope and Purpose.

(a) This regulation sets forth the policies and procedures that must be followed in order to compel an employee of the Federal Housing Finance Agency (FHFA) to produce records or information, or to provide testimony relating to the employee's official duties, in the context of a legal proceeding. Parties seeking records, information, or testimony must comply with these requirements when submitting demands or requests:

(b) FHFA intends these provisions to:

(1) Promote economy and efficiency in its programs and operations;

(2) Minimize the possibility of involving FHFA in controversial issues not related to its mission and functions;

(3) Maintain FHFA's impartiality;

(4) Protect employees from being compelled to serve as involuntary witnesses for wholly private interests, or as inappropriate expert witnesses regarding current law or the activities of FHFA; and

(5) Protect sensitive, confidential information and FHFA's deliberative processes.

(c) By providing these policies and procedures, FHFA does not waive the sovereign immunity of the United States.

(d) This part provides guidance for FHFA's internal operations. This part does not create any right or benefit, substantive or procedural, that a party may rely upon in any legal proceeding against the United States.

(e) The production of records, information, or testimony pursuant to this part, does not constitute a waiver by FHFA of any privilege.

§ 1215.2 Applicability.

(a) This regulation applies to demands or requests for records, information, or testimony, in legal proceedings in which FHFA is not a named party.

(b) This regulation does not apply to:

(1) Demands or requests for an FHFA employee to testify as to facts or events that are unrelated to his or her official duties or that are unrelated to the functions of FHFA;

(2) Requests for the release of non-exempt records under the Freedom of Information Act, 5 U.S.C. 552, or the Privacy Act, 5 U.S.C. 552a; or

(3) Congressional demands or requests for records or testimony.

§ 1215.3 Definitions.

As used in this part—

Demand means a subpoena, or an order or other command of a court or other competent authority, for the production of records, information, or testimony that is issued in a legal proceeding.

Employee means:

(1) Any current or former officer or employee of FHFA or of FHFA–OIG;

(2) Any other individual hired through contractual agreement by or on behalf of FHFA who has performed or is performing services under such an agreement for FHFA; and

(3) Any individual who has served or is serving in any consulting or advisory capacity to FHFA, whether formal or informal.

Federal Home Loan Bank means a bank established under the authority of 12 U.S.C. 1423(a).

FHFA means the Federal Housing Finance Agency including the FHFA–OIG.

FHFA Counsel means an attorney in FHFA's Office of the General Counsel.

General Counsel means FHFA's General Counsel or a person within FHFA's Office of General Counsel to whom the General Counsel has delegated responsibilities under this part.

Legal Proceeding means any matter before a court of law, administrative board or tribunal, commission, administrative law judge, hearing officer, or other body that conducts a legal or administrative proceeding. Legal proceeding includes all phases of litigation.

Produce means provide, disclose, expose, or grant access to.

Records or Information means, regardless of the person or entity in possession:

(1) All documents and materials that are FHFA agency records under the Freedom of Information Act, 5 U.S.C. 552;

(2) All other documents and materials contained in FHFA files; and

(3) All other information or materials acquired by an FHFA employee in the performance of his or her official duties or because of his or her official status.

Regulated entity has the same meaning as set forth in 12 U.S.C. 4502(20). For this regulation's purposes, ''regulated entity'' also includes—

(1) The Office of Finance; and

(2) Any current or former director, officer, employee, contractor or agent of a regulated entity.

Request means any informal request, by whatever method, in connection with a legal proceeding, seeking production of records, information, or testimony that has not been ordered by a court or other competent authority.

Testimony means any written or oral statements, including depositions, answers to interrogatories, affidavits, declarations, and recorded interviews made by an individual about FHFA information in connection with a legal proceeding.

§ 1215.4 General Prohibition.

(a) No employee, agent, regulated entity, the Office of Finance, or any other person or entity in possession of records or information may produce those records or information, or provide any testimony related to the records or information, in response to any demand or request without prior written approval to do so from the Director.

(b) Any person or entity that fails to comply with this part may be subject to the penalties provided in 18 U.S.C. 641 and other applicable laws. A current employee also may be subject to administrative or disciplinary proceedings.

§ 1215.5 Delegation.

To the extent permissible by statute, the Director may delegate his authority under this part to any FHFA employee and the General Counsel may delegate his authority under this part to any FHFA Counsel.

§ 1215.6 Factors FHFA May Consider.

The Director may grant an employee permission to testify regarding agency matters, and to produce records and information, in response to a demand or request. Among the relevant factors that the Director may consider in making this determination are whether:

(a) This part's purposes are met;

(b) FHFA has an interest in the decision that may be rendered in the legal proceeding;

(c) Approving the demand or request would assist or hinder FHFA in performing statutory duties or use FHFA resources;

(d) Production might assist or hinder employees in doing their work;

(e) The records, information, or testimony can be obtained from other sources. (Concerning testimony, ''other sources'' means a non-agency employee, or an agency employee other than the employee named).

(f) The demand or request is unduly burdensome or otherwise inappropriate under the rules of discovery or procedure governing the case or matter in which the demand or request arose;

(g) Production of the records, information, or testimony might violate or be inconsistent with a statute, Executive Order, regulation, or other legal authority;

(h) Production of the records, information, or testimony might reveal confidential or privileged information, trade secrets, or confidential commercial or financial information;

(i) Production of the records, information, or testimony might impede or interfere with an ongoing law enforcement investigation or proceedings, or compromise constitutional rights;

(j) Production of the records, information, or testimony might result in FHFA appearing to favor one litigant over another;

(k) The demand or request pertains to documents that were produced by another agency;

(l) The demand or request complies with all other applicable rules;

(m) The demand or request is sufficiently specific to be answered;

(n) The relevance of the records, information, or testimony to the purposes for which they are sought, and for which they may be used for substantive evidence;

(o) Production of the records, information, or employee testimony may implicate a substantial government interest; and

(p) Any other good cause.

§ 1215.7 Serving Demands and Submitting Requests.

(a) All demands and requests must be in writing.

(b) Demands must be served and requests must be submitted to the FHFA General Counsel at the following address: General Counsel, Federal Housing Finance Agency, Constitution Center, Eighth Floor, 400 Seventh Street, SW., Washington, DC 20024.

(c) Demands must not be served upon, nor requests submitted to any regulated entity for records, information, or testimony regardless of whether the records, information, or testimony sought are in the possession of, or known by, the regulated entity. If a regulated entity receives a request or demand for records, information, or testimony, the regulated entity must immediately notify the General Counsel and provide FHFA an opportunity to object to the demand or request before responding to the demand or request. Submitting a demand or request to a regulated entity may result in rejection of the demand or request under § 1215.9.

(d) If an employee receives a request or demand that is not properly routed through FHFA's General Counsel, as required under this section, the employee must promptly notify the General Counsel. An employee's failure to notify the General Counsel is grounds for discipline or other adverse action.

§ 1215.8 Timing and Form of Demands and Requests.

(a) A party seeking records, information, or testimony must submit a request and receive a rejection before making a demand for records, information, or testimony.

(b) A demand or request to FHFA must include a detailed description of the basis for the demand or request and comply with the requirements in § 1215.7.

(c) Demands and requests must be submitted at least 60 days in advance of the date on which the records, information, or testimony is needed. Exceptions to this requirement may be granted upon a showing of compelling need.

(d) A demand or request for testimony also must include an estimate of the amount of time that the employee will need to devote to the process of testifying (including anticipated travel time and anticipated duration of round trip travel), plus a showing that no document or the testimony of non-agency persons, including retained experts, could suffice in lieu of the employee's testimony.

(e) Upon submitting a demand or request seeking employee testimony, the requesting party must notify all other parties to the legal proceeding.

(f) After receiving notice of a demand or request for testimony, but before the testimony occurs, a party to the legal proceeding who did not join in the demand or request and who wishes to question the witness beyond the scope of the testimony sought must submit a separate demand or request within 60 days of receiving the notice required under paragraph (e) of this section and must then comply with paragraph (c) of this section.

(g) Every demand or request must include the legal proceeding's caption and docket number, the forum; the name, address, phone number, State Bar number, and, if available, electronic mail address of counsel to all parties to the legal proceeding (in the case of *pro-se* parties, substitute the name, address, phone number, and electronic mail address of the *pro-se* party); and a statement of the demanding or requesting party's interest in the case. In addition, the demanding or requesting party must submit a clear and concise written statement that includes: a summary of the legal and factual issues in the proceeding and a detailed explanation as to how the records, information or testimony will contribute substantially to the resolution of one or more specially identified issues in the legal proceeding. A copy of the complaint or charging document may accompany—but must not be substituted for—the required statement.

§ 1215.9 Failure to Meet this Part's Requirements.

FHFA may oppose any demand or request that does not meet the requirements set forth in this part.

§ 1215.10 Processing Demands and Requests.

(a) The Director will review every demand or request received and, in accordance with this regulation, determine whether, and under what conditions, to authorize an employee to produce records, information, or testimony.

(b) The Director will process demands and requests in the order in which they are received. The Director will ordinarily respond within 60 days from the date that the agency receives all information necessary to evaluate the demand or request. However, the time for response will depend upon the scope of the demand or request. The Director may respond outside of the 60-day period:

(1) Under exigent or unusual circumstances; or

(2) When FHFA must receive and process records or information in the possession, custody, or control of a third party.

(c) The Director may confer with counsel to parties to a legal proceeding about demands or requests made pursuant to this part. The conference may be *ex-parte.* Failure to confer in good faith, in order to enable the Director to make an informed determination, may justify rejection of the demand or request.

(d) The Director may rely on sources of information other than those provided by the demanding or requesting parties as bases for making a determination.

(e) The Director may grant a waiver of any requirement in this section to promote a significant interest of FHFA or the United States, or for other good cause.

§ 1215.11 FHFA Determination.

(a) The Director makes FHFA's determinations regarding demands and requests.

(b) The Director will notify the demanding or requesting party of FHFA's determination, the reasons for the approval or rejection of the demand or request, and any conditions that the Director may impose on the release of records, information, or testimony.

§ 1215.12 Restrictions That Apply to Testimony.

(a) The Director may impose conditions or restrictions on testimony, including but not limited to limiting the scope of testimony or requiring the demanding or requesting party and other parties to the legal proceeding to agree that the testimony transcript will be kept under seal or will only be used or made available in the particular legal proceeding for which testimony was requested. The Director may also require a copy of the transcript of testimony to be provided to FHFA at the demanding or requesting party's expense.

(b) The Director may offer an employee's written declaration in lieu of testimony.

(c) If authorized to testify pursuant to this part, an employee may testify as to

facts within his or her personal knowledge, but, unless specifically authorized to do so by the Director, the employee must not:

(1) Disclose confidential or privileged information; or

(2) Testify as an expert or opinion witness with regard to any matter arising out of the employee's official duties or FHFA's mission or functions. This provision does not apply to requests from the United States for expert or opinion testimony.

(d) The Director may assign FHFA Counsel to be present for an employee's testimony.

§ 1215.13 Restrictions That Apply to Records and Information.

(a) The Director may impose conditions or restrictions on the release of records and information, including but not limited to requiring that parties to the legal proceeding obtain a protective order or execute a confidentiality agreement to limit access and further disclosure, or that parties take other appropriate steps to comply with applicable privacy requirements. The terms of a protective order or confidentiality agreement must be acceptable to the Director. In cases where protective orders or confidentiality agreements have already been executed, the Director may condition the release of records and information on an amendment to the existing protective order or confidentiality agreement.

(b) If the Director so determines, original agency records may be presented for examination in response to a demand or request, but they are not to be presented as evidence or otherwise used in a manner by which they could lose their status as original records, nor are they to be marked or altered. In lieu of the original records, certified copies will be presented for evidentiary purposes.

(c) The scope of permissible production is limited to that set forth in the prior, written authorization granted by the Director.

(d) If records or information are produced in connection with a legal proceeding, the demanding or requesting party must:

(1) Promptly notify all other parties to the legal proceeding that the records or information are FHFA records or information and are subject to this part and any applicable confidentiality agreement or protective order;

(2) Provide copies of any confidentiality agreement or protective order to all other parties; and

(3) Retrieve the records or information from the court or other competent authority's file when the court or other competent authority no longer requires the records or information and certify that every party covered by a confidentiality agreement, protective order, or other privacy protection has destroyed all copies of the records or information.

§ 1215.14 Procedure in the Event of an Adverse FHFA Determination.

(a) *Procedure for seeking reconsideration of FHFA's determination.* A demanding or requesting party seeking reconsideration of FHFA's rejection of a demand or request, or of any restrictions on receiving records, information, or testimony, may seek reconsideration of the rejection or restrictions as follows—

(1) *Notice of Intention to Petition for Reconsideration.* The aggrieved demanding or requesting party may seek reconsideration by filing a written Notice of Intention to Petition for Reconsideration (Notice) within 10 business days of the date of FHFA's determination. The Notice must identify the petitioner, the determination for which reconsideration is being petitioned, and any dates (such as deposition, hearing, or court dates) that are significant to petitioner. The Notice must be served in accordance with § 1215.7.

(2) *Petition for Reconsideration.* Within five business days of filing Notice, the petitioner must file a Petition for Reconsideration (Petition) in accordance with § 1215.7. The Petition must contain a clear and concise statement of the basis for the reconsideration with supporting authorities. Determinations about petitions for reconsideration are within the discretion of the FHFA Director, and are final.

(b) *Prerequisite to judicial review.* Pursuant to section 704 of the Administrative Procedure Act, 5 U.S.C. 704, a petition to FHFA for reconsideration of a final determination made under the authority of this part is a prerequisite to judicial review.

§ 1215.15 Conflicting Court Order.

Notwithstanding FHFA's rejection of a demand for records, information, or testimony, if a court or other competent authority orders an FHFA employee to comply with the demand, the employee must promptly notify FHFA's General Counsel of the order, and the employee must respectfully decline to comply, citing *United States ex rel. Touhy* v. *Ragen,* 340 U.S. 462 (1951). An employee's failure to notify the General Counsel of a court or other authority's order is grounds for discipline or other adverse action.

§ 1215.16 Fees.

(a) The Director may condition the production of records, information, or an employee's appearance on advance payment of reasonable costs to FHFA, which may include but are not limited to those associated with employee search time, copying, computer usage, and certifications.

(b) Witness fees will include fees, expenses, and allowances prescribed by the rules applicable to the particular legal proceeding. If no fees are prescribed, FHFA will base fees on the rule of the federal district court closest to the location where the witness will appear. Such fees may include but are not limited to time for preparation, travel, and attendance at the legal proceeding.

Dated: February 2, 2013.

Edward J. DeMarco,

Acting Director, Federal Housing Finance Agency.

[FR Doc. 2013–02908 Filed 2–7–13; 8:45 am]

BILLING CODE 8070–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0088; Directorate Identifier 2011–NM–233–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede an existing airworthiness directive (AD) that applies to all Airbus Model A318, A319, A320, and A321 series airplanes. The existing AD currently requires repetitive inspections of the upper support of the nose landing gear (NLG), and related investigative and corrective actions if necessary; and also provides an optional terminating action for the repetitive inspections. Since we issued that AD, we have determined that previously allowed terminating actions no longer address the unsafe condition and that a new terminating action is necessary. This proposed AD would require installing a new enhanced manufacturing and maintainability (EMM) braking and steering control unit (BSCU) standard and adds airplanes to

the applicability. We are proposing this AD to prevent landings with the NLG turned 90 degrees from centerline, which could result in reduced controllability of the airplane.

DATES: We must receive comments on this proposed AD by March 25, 2013.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Airbus, Airworthiness Office—EAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone (425) 227–1405; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2013–0088; Directorate Identifier 2011–NM–233–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

On August 17, 2007, we issued AD 2007–18–09, Amendment 39–15189 (72 FR 51164, September 6, 2007), which superseded AD 2005–24–06, Amendment 39–14386 (70 FR 70715, November 23, 2005). That AD required actions intended to address an unsafe condition on the products listed above.

Since we issued AD 2007–18–09, Amendment 39–15189 (72 FR 51164, September 6, 2007), The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2011–0201, dated October 13, 2011 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> In 2005, an A320 aeroplane experienced a landing with the Nose Landing Gear (NLG) wheels rotated at 90 degrees to the aeroplane centreline.
>
> Investigation showed that the upper support of the NLG shock absorber was damaged and the anti-rotation lugs were ruptured. This caused the nose wheels to lose their centred position reference. The affected Braking and Steering Control Unit (BSCU) had logged a steering system fault because hydraulic power was not available at the time of steering system checks, therefore the BSCU was not able to proceed with the re-centring of the wheels. Failure to centre the NLG wheels correctly may result in a failure of the NLG to retract.
>
> To prevent further landing incidents with NLG wheels rotated at 90 degrees, DGAC France issued AD F–2005–191 [which corresponds to FAA AD 2005–24–06, Amendment 39–14386 (70 FR 70715, November 23, 2005)] to require the implementation of an operational procedure and the accomplishment of certain maintenance actions.
>
> EASA AD 2006–0174, [which corresponds to FAA AD 2007–18–09, Amendment 39–15189 (72 FR 51164, September 6, 2007)] which superseded AD F–2005–191, was issued to extend the applicability and to introduce repetitive boroscope inspections of the NLG upper support lugs and cylinder lugs which have been driven by EMM BSCU L4.1 (Part Number (P/N) E21327001) or L4.5 (P/N E21327003) and, corrective actions, depending on findings.
>
> Since that AD was issued, Airbus has demonstrated the acceptability of installing EMM BSCU L4.9B (P/N E21327006 or P/N E21327106) or conventional BSCU std 10 (P/N C202163392E34) or conventional BSCU std 10.1 (P/N C202163392E35) as terminating action for the actions required by EASA AD 2006–0174, for aeroplanes fitted with twin wheel Main Landing Gear (MLG) units.
>
> For the reasons described above, this AD retains some of the requirements of EASA AD 2006–0174, which is superseded, extends the applicability to all A318, A319, A320 and A321 aeroplanes, requires the installation of BSCU L4.9B, or BSCU std 10, or BSCU std 10.1 for in service aeroplanes fitted with twin wheel MLG, which constitutes terminating action for the repetitive inspections and checks required by this AD.
>
> Installation of a NLG with new upper support anti-rotation lugs and new cylinders lugs, or installation of a NLG for which it can be demonstrated that it was never driven by EMM BSCU L4.1 or L4.5, is no longer considered as terminating action for the requirements of this AD.

The unsafe condition is the NLG turning 90 degrees from centerline, which could result in reduced controllability of the airplane. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Airbus has issued the following service bulletins.

- Airbus Mandatory Service Bulletin A320–32–1310, Revision 01, dated June 23, 2011.
- Airbus Mandatory Service Bulletin A320–32–1336, Revision 01, dated January 10, 2008.
- Airbus Service Bulletins A320–32–1350, dated July 31, 2008.
- Airbus Service Bulletin A320–32–1360, dated March 18, 2009.
- Airbus Service Bulletin A320–32–1369, Revision 01, dated March 31, 2010.
- Airbus Service Bulletin A320–32–1387, dated April 7, 2011.

The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this

AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between This AD and the MCAI or Service Information

Airbus Mandatory Service Bulletin A320–32–1310, Revision 01, dated June 23, 2011, specifies to use Airbus recommendations when restoring the NLG, but this proposed AD would require restoring the NLG in accordance with a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA) (or its delegated agent).

The MCAI permits accomplishment of MCAI paragraph 1.1 by inserting a copy of certain Airbus airplane flight manual (AFM) temporary revisions into the AFM. We have not included that provision in this proposed AD, since the temporary revisions have already been incorporated into the AFM.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 755 products of U.S. registry.

The actions that are required by FAA AD 2007–18–09, Amendment 39–15189 (72 FR 51164, September 6, 2007), and retained in this proposed AD take about 3 work-hours per product, at an average labor rate of $85 per work hour. Based on these figures, the estimated cost of the currently required actions is $255 per product.

We estimate that it would take about 35 work-hours per product to comply with the new basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these parts. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $2,246,125, or $2,975 per product.

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this proposed AD. We have no way of determining the number of products that may need these actions.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing airworthiness directive (AD) 2007–18–09, Amendment 39–15189 (72 FR 51164, September 6, 2007), and adding the following new AD:

Airbus: Docket No. FAA–2013–0088; Directorate Identifier 2011–NM–233–AD.

(a) Comments Due Date

We must receive comments by March 25, 2013.

(b) Affected ADs

This AD supersedes AD 2007–18–09, Amendment 39–15189 (72 FR 51164, September 6, 2007).

(c) Applicability

This AD applies to the Airbus airplanes listed in paragraphs (c)(1), (c)(2), (c)(3), and (c)(4) of this AD; certificated in any category; all serial numbers.

(1) Model A318–111, –112, –121, and –122 airplanes.

(2) Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes.

(3) Model A320–111, –211, –212, –214, –231, –232, and –233 airplanes.

(4) Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 32, Landing gear.

(e) Reason

This AD was prompted by a report of an airplane landing with the nose landing gear (NLG) turned 90 degrees from centerline, and from additional reports of upper support anti-rotation lugs of the NLG rupturing in service. We are issuing this AD to prevent landings with the NLG turned 90 degrees from centerline, which could result in reduced controllability of the airplane.

(f) Compliance

You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

(g) Retained Records Review

This paragraph restates the requirements of paragraph (f) of AD 2007–18–09, Amendment 39–15189 (72 FR 51164, September 6, 2007). Within 5 days after November 30, 2005 (the effective date of AD 2005–24–06, Amendment 39–14386 (70 FR 70715, November 23, 2005)), perform a records review to determine whether the airplane is equipped with or has ever been equipped with an enhanced manufacturing and maintainability (EMM) braking and steering control unit (BSCU) part number (P/N) E21327001 (standard L4.1, installed by Airbus Modification 26965, or Airbus Service Bulletin A320–32–1912) or P/N E21327003 (standard L4.5, installed by Airbus Modification 33376, or Airbus Service Bulletin A320–32–1261). Airbus Service Bulletin A320–32–1310, dated February 8, 2006, is one approved method for doing the records review.

(h) Retained Statement of No Further Action Required

This paragraph restates the requirements of paragraph (g) of AD 2007–18–09, Amendment 39–15189 (72 FR 51164, September 6, 2007). For airplanes on which a records review required by paragraph (g) of this AD conclusively determines that the airplane is not and never has been equipped with a BSCU P/N E21327001 or P/N E21327003, no further action is required by paragraphs (i), (j), (k), (l), and (m) of this AD.

(i) Retained Airplane Flight Manual (AFM) Revision

This paragraph restates the requirements of paragraph (h) of AD 2007–18–09, Amendment 39–15189 (72 FR 51164, September 6, 2007). For airplanes that are not specified in paragraph (h) of this AD and on which Airbus Modification 31152 has not been incorporated in production (i.e., applicable only to aircraft with steering powered by the green hydraulic system): Within 10 days after November 30, 2005 (the effective date of AD 2005–24–06, Amendment 39–14386 (70 FR 70715, November 23, 2005)), revise the Limitation Section of the Airbus A318/319/320/321 Aircraft Flight Manual (AFM) to include the following information. This may be done by inserting a copy of this AD into the AFM:

The ECAM message, in case of a nose wheel steering failure, will be worded as follows:

—''WHEEL N/W STRG FAULT'' for aircraft with the FWC E3 and subsequent standards

—''WHEEL N.W. STEER FAULT'' for aircraft with the FWC E2 Standard.

■ If the L/G SHOCK ABSORBER FAULT ECAM caution is triggered at any time in flight, and the WHEEL N/W STRG FAULT ECAM caution is triggered after the landing gear extension:

When all landing gear doors are indicated closed on ECAM WHEEL page, reset the BSCU:

—A/SKID&N/W STRG---------- OFF THEN ON

If the WHEEL N/W STRG FAULT ECAM caution is no longer displayed, this indicates a successful nose wheel re-centering and steering recovery.

—Rearm the AUTO BRAKE, if necessary.

If the WHEEL N/W STRG FAULT ECAM caution remains displayed, this indicates that the nose wheel steering remains lost, and that the nose wheels are not centered.

—During landing, delay nose wheel touchdown for as long as possible.

—Refer to the ECAM STATUS.

■ If the WHEEL N/W STRG FAULT ECAM caution appears, without the L/G SHOCK ABSORBER FAULT ECAM caution:

—No specific crew action is requested by the WHEEL N/W STRG FAULT ECAM caution procedure.

—Refer to the ECAM STATUS.

Accomplishment of the actions required by paragraph (r) of this AD terminates the requirements of this paragraph, and the AFM limitation required by this paragraph must be removed.

Note 1 to paragraph (i) of this AD: When a statement identical to that in paragraph (i) of this AD has been included in the general revisions of the AFM, the general revisions may be inserted into the AFM, and the copy of this AD or AD 2007–18–09, Amendment 39–15189 (72 FR 51164, September 6, 2007), may be removed from the AFM.

(j) Retained Inspection Thresholds

This paragraph restates the requirements of paragraph (i) of AD 2007–18–09, Amendment 39–15189 (72 FR 51164, September 6, 2007). For airplanes that are not specified in paragraph (h) of this AD, at the earlier of the times specified in paragraphs (j)(1) and (j)(2) of this AD: Do a special detailed inspection (boroscopic) for broken or cracked NLG upper support lugs and missing cylinder lugs, and do all applicable related investigative/corrective actions before further flight. Do all actions in accordance with Airbus Technical Note 957.1901/05, dated October 18, 2005; or the Accomplishment Instructions of Airbus Service Bulletin A320–32–1310, dated February 8, 2006. After October 11, 2007 (the effective date of AD 2007–18–09), only Airbus Service Bulletin A320–32–1310, dated February 8, 2006, may be used. Where Airbus Service Bulletin A320–32–1310, dated February 8, 2006, specifies that restoring the NLG is necessary in accordance with Airbus recommendations, this AD requires restoring the NLG in accordance with a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA) (or its delegated agent). Repeat the inspection thereafter at the applicable interval specified in paragraph (k) or (l) of this AD until the inspection required by paragraph (t) of this AD is accomplished.

(1) Within 100 flight cycles following an electronic centralized aircraft monitoring (ECAM) caution ''L/G SHOCK ABSORBER FAULT'' associated with at least one of the following centralized fault display system (CFDS) messages specified in paragraph (j)(1)(i), (j)(1)(ii), or (j)(1)(iii) of this AD. As of the effective date of this AD, for the conditions specified in paragraph (j)(1) of this AD, do the actions required by paragraph (r) of this AD.

(i) ''N L/G EXT PROX SNSR 24GA TGT POS.''

(ii) ''N L/G EXT PROX SNSR 25GA TGT POS.''

(iii) ''N L/G SHOCK ABSORBER FAULT 2526GM.''

(2) At the later of the times specified in paragraphs (j)(2)(i) and (j)(2)(ii) of this AD.

(i) Within 20 months, 6,000 flight hours, or 4,500 flight cycles since the date of issuance of the original French standard airworthiness certificate, or the original French export certificate of airworthiness, whichever occurs first.

(ii) Within 6 months, 1,800 flight hours, or 1,350 flight cycles after October 11, 2007 (the effective date of AD 2007–18–09, Amendment 39–15189 (72 FR 51164, September 6, 2007)), whichever occurs first.

(k) Retained Repetitive Inspection Intervals for BSCU Standard L4.1 or L4.5

This paragraph restates the requirements of paragraph (j) of AD 2007–18–09, Amendment 39–15189 (72 FR 51164, September 6, 2007). For airplanes not specified in paragraph (h) of this AD that are equipped with EMM BSCU standard L4.1 or L4.5: Repeat the inspection specified in paragraph (j) of this AD thereafter at intervals not to exceed the earliest of 6 months; 1,800 flight hours; 1,350 flight cycles; or 100 flight cycles following certain ECAM cautions and CFDS messages, as specified in paragraph (j)(1) of this AD.

(l) Retained Repetitive Inspection Intervals for BSCU Standard L4.8 or Non-EMM BSCU

This paragraph restates the requirements of paragraph (k) of AD 2007–18–09, Amendment 39–15189 (72 FR 51164, September 6, 2007). For airplanes not specified in paragraph (h) of this AD that are equipped with EMM BSCU standard L4.8 or a non-EMM BSCU: Repeat the inspection specified in paragraph (j) of this AD thereafter at intervals not to exceed the earliest of 20 months; 6,000 flight hours; 4,500 flight cycles; or 100 flight cycles following certain ECAM cautions and CFDS messages, as specified in paragraph (j)(1) of this AD.

(m) Retained Optional Terminating Action With Limiting Date Restriction

This paragraph restates the requirements of paragraph (l) of AD 2007–18–09, Amendment 39–15189 (72 FR 51164, September 6, 2007) with a limiting date restriction. For airplanes that are not specified in paragraph (h) of this AD: Installation of an NLG with new upper support anti-rotation lugs and new cylinder lugs, or installation of an NLG that was never driven by EMM BSCU standard L4.1 or L4.5; combined with installation of EMM BSCU standard L4.8 or a non-EMM BSCU; before the effective date of this AD; constitutes terminating action for the requirements of paragraphs (g), (h), (i), (j), (k), and (l) of this AD. Do the installations in accordance with a method approved by either the Manager, International Branch, ANM–116; or the EASA (or its delegated agent). Chapter 32 of the Airbus A318/A319/A320/A321 Aircraft Maintenance Manual (AMM) is one approved method for doing the installations before the effective date of this AD.

(n) Retained Statement of No Reporting Required

This paragraph restates the requirements of paragraph (m) of AD 2007–18–09, Amendment 39–15189 (72 FR 51164, September 6, 2007). Although Airbus Service Bulletin A320–32–1310, dated February 8, 2006, specifies sending certain inspection results to Airbus, this AD does not include that requirement.

(o) Part Number Identification

For the purpose of this AD, the following part numbers are identified.

(1) P/N E21327001: installed by Airbus Modification 26965 or by Airbus Service Bulletin A320–32–1912 in service: EMM BSCU L4.1.

(2) P/N E21327003: installed by Airbus Modification 33376 or Airbus Service

Bulletin A320–32–1261 in service: EMM BSCU L4.5.

(3) P/N E21327004: installed by Airbus modification 35216 or Airbus Service Bulletin A320–32–1305 or Airbus Service Bulletin A320–32–1343/AOT A320–32A1343 in service: EMM BSCU L4.8.

(4) P/N E213270B1: installed by Airbus modification 31931 or Airbus Service Bulletin A320–32–1206: EMM BSCU L5–2.

(5) P/N E21327006: installed by Airbus modification 38973 or Airbus Service Bulletin A320–32–1350 or Airbus Service Bulletin A320–32–1361: EMM BSCU L4.9B.

(6) P/N E21327106: installed by Airbus modification 151575 or Airbus Service Bulletin A320–32–1387: EMM BSCU L4.9B.

(7) P/N C202163392E34: installed by Airbus Service Bulletin A320–32–1336 or Airbus Service Bulletin A320–32–1360: conventional BSCU standard (std) 10.

(8) P/N C202163392E35: installed by Airbus Service Bulletin A320–32–1369: conventional BSCU std 10.1.

(p) Records Review

Within 5 days after the effective date of this AD: Perform a records review to determine whether the airplane is equipped with or has ever been equipped with an EMM BSCU having P/N E21327001 (standard L4.1, installed by Airbus modification 26965, or Airbus Service Bulletin A320–32–1912) or P/N E21327003 (standard L4.5, installed by Airbus modification 33376, or Airbus Service Bulletin A320–32–1261), or P/N E21327004 (standard L4.8, installed by Airbus modification 35216, or Airbus Service Bulletin A320–32–1305, or Airbus Service Bulletin A320–32–1343/AOT A320–32A1343), or P/N E213270B1 (standard L5–2, installed by Airbus modification 31931, or Airbus Service Bulletin A320–32–1206).

Note 2 to paragraph (p) of this AD: Accomplishment of the actions specified in Airbus Mandatory Service Bulletin A320–32–1310, Revision 01, dated June 23, 2011, before the effective date of this AD, provides a method for doing the records review.

(q) No Further Action Required for Certain Paragraphs

For airplanes on which a records review required by paragraph (p) of this AD conclusively determines that the airplane is not and never has been equipped with an EMM BSCU having P/N E21327001, or P/N E21327003, or P/N E21327004, or P/N E213270B1, no further action is required by paragraphs (r) and (s) of this AD.

(r) Airplane Flight Manual Revision

For airplanes that are not identified in paragraph (q) of this AD and on which Airbus Modification 31152 has not been incorporated in production (i.e., applicable only to aircraft with steering powered by the green hydraulic system): Within 10 days after the effective date of this AD, revise the Limitation Section of the Airbus A318/319/320/321 AFM to include the following information. This revision may be done by inserting a copy of this AD into the AFM.

The ECAM message, in case of a nose wheel steering failure, will be worded as follows:

—''WHEEL N/W STRG FAULT'' for airplanes with Flight Warning Computer (FWC) software post E3P.

—''WHEEL N.W. STEER FAULT'' for airplanes with FWC software pre E3P.

■ If the L/G SHOCK ABSORBER FAULT ECAM caution is triggered at any time in flight, and the WHEEL N/W STRG FAULT ECAM caution is triggered after the landing gear extension:

• When all landing gear doors are indicated closed on ECAM WHEEL page, reset the BSCU:

—A/SKID&N/W STRG---------- OFF THEN ON

• If the WHEEL N/W STRG FAULT ECAM caution is no longer displayed, this indicates a successful nose wheel re-centering and steering recovery.

—Rearm the AUTO BRAKE, if necessary.

• If the WHEEL N/W STRG FAULT ECAM caution remains displayed, this indicates that the nose wheel steering remains lost, and that the nose wheels are not centered.

—During landing, delay nose wheel touchdown for as long as possible.

—Refer to the ECAM STATUS.

■ If the WHEEL N/W STRG FAULT ECAM caution appears, without the L/G SHOCK ABSORBER FAULT ECAM caution:

—No specific crew action is requested by the WHEEL N/W STRG FAULT ECAM caution procedure.

—Refer to the ECAM STATUS.

Note: For airplanes fitted with pre FWC E3P standard, read N.W STEER instead of N/W STRG.

Accomplishment of the actions required by this paragraph terminates the requirements of paragraph (i) of this AD and the AFM revision required by paragraph (i) of this AD must be removed.

Note 3 to paragraph (r) of this AD: When a statement identical to that in paragraph (r) of this AD has been included in the general revisions of the AFM, the general revisions may be inserted into the AFM, and the copy of this AD may be removed from the AFM.

(s) Inspection Following Certain Centralized Fault Display System Messages

(1) For airplanes other than those identified in paragraph (q) of this AD: Within 100 flight cycles following an ECAM caution ''L/G SHOCK ABSORBER FAULT'' associated with at least one of the following CFDS messages specified in paragraph (s)(1)(i), (s)(1)(ii), or (s)(1)(iii) of this AD, do the actions in paragraph (s)(2) of this AD.

(i) ''N L/G EXT PROX SNSR 24GA TGT POS.''

(ii) ''N L/G EXT PROX SNSR 25GA TGT POS.''

(iii) ''N L/G SHOCK ABSORBER FAULT 2526GM.''

(2) For airplanes identified in paragraph (s)(1) of this AD: Do the actions specified in paragraphs (s)(2)(i) and (s)(2)(ii) of this AD.

(i) Check the NLG strut inflation pressure, weight-off- and weight-on-wheels, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A320–32–1310, Revision 01, dated June 23, 2011, and before further flight, do all applicable corrective actions and adjustments, in accordance with Airbus A318/A319/A320/A321, Task 12–12–32–610–001–A Check NLG Shock Absorber Fluid Level and Charge Pressure (''Two-Point Check''—Aircraft on Jacks to start), Revision August 1, 2012.

(ii) Do a boroscopic inspection for broken or cracked NLG upper support lugs and missing or cracked cylinder lugs, and do all applicable related investigative and corrective actions before further flight. Do all actions in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A320–32–1310, Revision 01, dated June 23, 2011. Where Airbus Mandatory Service Bulletin A320–32–1310, Revision 01, dated June 23, 2011, specifies restoring the NLG in accordance with Airbus recommendations, this AD requires restoring the NLG before further flight, in accordance with a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the EASA (or its delegated agent).

(t) Initial Boroscopic Inspection

At the applicable times specified in paragraphs (t)(1) and (t)(2) of this AD: Do a boroscopic inspection for broken or cracked NLG upper support lugs and missing or cracked cylinder lugs, and do all applicable related investigative and corrective actions before further flight. Do all actions in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A320–32–1310, Revision 01, dated June 23, 2011. Where Airbus Mandatory Service Bulletins A320–32–1310, Revision 01, dated June 23, 2011, specifies restoring the NLG in accordance with Airbus recommendations, this AD requires restoring the NLG before further flight, in accordance with a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the EASA (or its delegated agent). Accomplishment of the actions required by this paragraph terminate the requirements of paragraphs (j), (k), and (l) of this AD.

(1) For airplanes fitted with twin wheel main landing gear (MLG) that have been equipped with EMM BSCU standard L4.1, L4.5, or L4.8: At the later of the times specified in paragraphs (t)(1)(i) and (t)(1)(ii) of this AD.

(i) Within 20 months, 6,000 flight hours, or 4,500 flight cycles since first flight of the airplane, whichever occurs first.

(ii) Within 6 months, or 1,800 flight hours, or 1,350 flight cycles after the effective date of this AD, whichever occurs first.

(2) For airplanes fitted with bogie MLG: At the later of the times specified in paragraphs (t)(2)(i) and (t)(2)(ii) of this AD.

(i) Within 20 months, or 6,000 flight hours, or 4,500 flight cycles after the installation of EMM BSCU standard L5–2, whichever occurs first.

(ii) Within 6 months, or 1,800 flight hours, or 1,350 flight cycles after the effective date of this AD, whichever occurs first.

(u) Repetitive Boroscopic Inspections

After accomplishing the inspection specified in paragraph (t) of this AD: Repeat

the inspection required by paragraph (t) of this AD thereafter at the applicable interval specified in paragraphs (u)(1), (u)(2), and (u)(3) of this AD.

(1) For airplanes fitted with twin wheel MLG that have been equipped with EMM BSCU standard L4.8: At intervals not to exceed 20 months, or 6,000 flight hours, or 4,500 flight cycles, whichever occurs first.

(2) For airplanes fitted with twin wheel MLG that have been equipped with EMM BSCU standard L4.1 or L4.5: At intervals not to exceed 6 months, or 1,800 flight hours, or 1,350 flight cycles, whichever occurs first.

(3) For airplanes fitted with bogie MLG: At intervals not to exceed 20 months, or 6,000 flight hours, or 4,500 flight cycles, whichever occurs first.

(v) Modification

For airplanes fitted with twin wheel MLG: Within 6 months after the effective date of this AD, modify the airplane by installing EMM BSCU standard L4.9B, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–32–1350, dated July 3, 2008.

(w) Optional Method of Modification

Doing a modification specified in paragraph (w)(1), (w)(2), or (w)(3) of this AD, is acceptable for compliance with the requirements of paragraph (v) of this AD.

(1) Modification of the airplane by installing EMM BSCU standard L4.9B, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–32–1387, dated April 7, 2011.

(2) Modification of the airplane by installing conventional EMM BSCU standard 10, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–32–1360, dated March 18, 2009; or Airbus Mandatory Service Bulletin A320–32–1336, Revision 01, dated January 10, 2008.

(3) Modification of the airplane by installing conventional EMM BSCU standard 10.1 in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–32–1369, Revision 01, dated March 31, 2010.

(x) Terminating Action

In-service modification of an airplane fitted with twin wheel MLG as required by paragraph (v) of this AD constitutes terminating action for the initial and repetitive inspections required by paragraph (t) of this AD. In addition, the AFM changes required by paragraph (r) of this AD may be removed from the AFM; and the requirements of paragraph (s) of this AD are no longer required.

(y) Exemption From Certain Actions

Except for paragraph (y) of this AD, airplanes that have been delivered with Airbus modification 38973 and/or Airbus modification 151575 that install EMM BSCU standard L4.9B are not affected by the requirements of this AD, provided that no installation of previous EMM BSCU standards L4.1, L4.5, or L4.8 has been performed since the airplane first flight.

(z) Parts Installation

For airplanes that do not have EMM BSCU L4.1, or EMM BSCU L4.5, or EMM BSCU L4.8 installed: As of the effective date of this AD, no person may modify an airplane by installing EMM BSCU standards L4.1, L4.5, or L4.8 on any airplane.

(aa) Credit for Previous Actions

(1) This paragraph restates the requirements of paragraph (n) of AD 2007–18–09, Amendment 39–15189 (72 FR 51164, September 6, 2007). This paragraph provides credit for the inspections required by paragraph (j) of this AD, if those inspections were performed before October 11, 2007 (the effective date of AD 2007–18–09, Amendment 39–15189 (72 FR 51164, September 6, 2007)) using Chapter 12, Subject 12–14–32 of the Airbus A318/A319/A320/A321 AMM, as revised by Airbus A318/A319/A320/A321 AMM Temporary Revision 12–001, dated November 13, 2005.

(2) This paragraph provides credit for the inspections and related investigative/corrective actions required by paragraphs (j), (k), and (l) of this AD, if those inspections were performed before the effective date of this AD using Airbus Service Bulletin A320–32–1310, dated February 8, 2006.

(3) This paragraph provides credit for the modifications specified in paragraph (w)(2) of this AD, if those modifications were performed before the effective date of this AD using Airbus Mandatory Service Bulletin A320–32–1336, dated September 19, 2007.

(4) This paragraph provides credit for the modifications required by paragraph (w)(3) of this AD, if those modifications were performed before the effective date of this AD using Airbus Service Bulletin A320–32–1369, dated March 22, 2009.

(bb) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone (425) 227–1405; fax (425) 227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD. AMOCs approved previously in accordance with AD 2007–18–09, Amendment 39–15189 (72 FR 51164, September 6, 2007), are not approved as AMOCs with this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(cc) Related Information

(1) Refer to MCAI EASA Airworthiness Directive 2011–0201, dated October 13, 2011, and the service information service information identified in paragraphs (cc)(1)(i) through (cc)(1)(viii) for related information.

(i) Airbus A318/A319/A320/A321, Task 12–12–32–610–001–A Check NLG Shock Absorber Fluid Level and Charge Pressure (''Two-Point Check''—Aircraft on Jacks to start), Revision August 1, 2012.

(ii) Airbus Mandatory Service Bulletin A320–32–1310, Revision 01, dated June 23, 2011.

(iii) Airbus Mandatory Service Bulletin A320–32–1336, Revision 01, dated January 10, 2008.

(iv) Airbus Service Bulletin A320–32–1350, dated July 31, 2008.

(v) Airbus Service Bulletin A320–32–1360, dated March 18, 2009.

(vi) Airbus Service Bulletin A320–32–1369, Revision 01, dated March 31, 2010.

(vii) Airbus Service Bulletin A320–32–1387, dated April 7, 2011.

(viii) Airbus Technical Note 957.1901/05, dated October 18, 2005.

(2) For service information identified in this AD, contact Airbus, Airworthiness Office—EAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on January 31, 2013.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–02898 Filed 2–7–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0090; Directorate Identifier 2012–NM–149–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain

The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–300, 747–400, 747–400D, and 747SP series airplanes. This proposed AD was prompted by reports of worn or incorrectly assembled latches on main deck escape slides installed on airplane doors. This proposed AD would require determining if the latches are correctly assembled; and corrective actions if necessary. This proposed AD also would require, for certain airplanes, modifications to the escape slide/rafts and escape slides. We are proposing this AD to prevent a latch hook moving from closed to open in an escape slide/raft or escape slide, which could result in the escape slide/raft or escape slide not deploying correctly in an emergency, or releasing/inflating into the passenger cabin and causing injury to passengers and crew.

DATES: We must receive comments on this proposed AD by March 25, 2013.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For Boeing service information identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* For Goodrich service information identified in this proposed AD, contact Goodrich Corporation, Aircraft Interior Products, ATTN: Technical Publications, 3414 South Fifth Street, Phoenix, AZ 85040–1169; telephone 602–243–2200; Internet *http://www.goodrich.com/TechPubs.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Sarah Piccola, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6483; fax: 425–917–6590; email: *sarah.piccola@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2013–0090; Directorate Identifier 2012–NM–149–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We received reports that, in service, latches in the main deck escape slide/rafts and escape slides installed on airplane doors were not fully closed. The current latch design uses friction to keep the latch hook closed. Corrosion and worn parts reduce friction between the parts of the latch that keep it closed. The new latch design has a retention feature to make sure the latch stays closed. A latch hook moving from the closed to the open position in an escape slide/raft or escape slide, if not corrected, could result in an escape slide/raft or escape slide not deploying correctly in an emergency, or releasing/inflating into the passenger cabin and causing injury to passengers and crew.

Relevant Service Information

We reviewed Boeing Special Attention Service Bulletin 747–25–3428, Revision 3, dated June 14, 2012. For information on the procedures and compliance times, see this service information at *http://www.regulations.gov* by searching for Docket No. FAA–2013–0090.

Concurrent Service Information

Boeing Special Attention Service Bulletin 747–25–3428, Revision 3, dated June 14, 2012, specifies concurrent or prior accomplishment of Boeing Service Bulletin 747–25–2425, Revision 1, dated September 7, 1979. For information on the procedures, see this service information at *http://www.regulations.gov* by searching for Docket No. FAA 2013 0090.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously.

The phrase ''related investigative actions'' might be used in this proposed AD. ''Related investigative actions'' are follow-on actions that (1) are related to the primary action, and (2) are actions that further investigate the nature of any condition found. Related investigative actions in an AD could include, for example, inspections.

In addition, the phrase ''corrective actions'' might be used in this proposed AD. ''Corrective actions'' are actions that correct or address any condition found. Corrective actions in an AD could include, for example, repairs.

Costs of Compliance

We estimate that this proposed AD affects 121 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Determine if latches are correctly assembled.	1 work-hour × $85 per hour = $85.	$0	$85	$10,285.
Option to rework/replace latches instead of determining if latches are correctly assembled.	Between 3 and 24 work-hours × $85 per hour = Between $255 and $2,040.	$286 per latch	Between $541 and $2,326	Between $65,461 and $281,446.

We estimate the following costs to do any necessary replacements that would be required based on the results of the proposed latch assembly determination. We have no way of determining the number of aircraft that might need this replacement:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Corrective action	Between 3 and 24 work-hours × $85 per hour = Between $255 and $ 2,040.	$286 per latch	Between $541 and $2,326.

According to the manufacturer, all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

The Boeing Company: Docket No. FAA–2013–0090; Directorate Identifier 2012–NM–149–AD.

(a) Comments Due Date

We must receive comments by March 25, 2013.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–300, 747–400, 747–400D, and 747SP series airplanes; certificated in any category; as identified in Boeing Special Attention Service Bulletin 747–25–3428, Revision 3, dated June 14, 2012; except for Groups 3–4, Configuration 2, and Group 9, Configuration 2, airplanes.

(d) Subject

Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 25, Equipment/furnishings.

(e) Unsafe Condition

This AD was prompted by reports of worn or incorrectly assembled latches on main deck escape slides installed on airplane doors. We are issuing this AD to prevent a latch hook moving from closed to open in an escape slide/raft or escape slide, which could result in the escape slide/raft or escape slide not deploying correctly in an emergency, or releasing/inflating into the passenger cabin and causing injury to passengers and crew.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Replacement or Rework of Escape Slide Latch Assembly

Within 48 months after the effective date of this AD: Determine if the latches in the main deck escape slide/rafts and the escape slides installed on the airplane doors are correctly assembled, and do all applicable corrective actions, in accordance with the

Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–25–3428, Revision 3, dated June 14, 2012. Do all applicable corrective actions before further flight. Options provided in Boeing Special Attention Service Bulletin 747–25–3428, Revision 3, dated June 14, 2012, for determining the correct assembly of the latches are acceptable for the corresponding requirement of this paragraph.

(h) Concurrent Requirements

For Groups 1, 5, 10, and 13 airplanes, as identified in Boeing Special Attention Service Bulletin 747–25–3428, Revision 3, dated June 14, 2012: Prior to or concurrently with accomplishing the actions required by paragraph (g) of this AD, replace the packboard cap nuts with flush-type inserts, reinforce the lower packboard support bracket attachments, install hooks, modify the lower liner of the main entry door and packboard, and remove the ''Press to Test'' circuit panel and associated circuitry, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 747–25–2425, Revision 1, dated September 7, 1979.

(i) Credit for Previous Actions

This paragraph provides credit for the applicable concurrent actions required by paragraph (h) of this AD, if those actions were performed before the effective date of this AD using Boeing Service Bulletin 747–25–2425, dated August 25, 1978, which is not incorporated by reference in this AD.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO) FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in the Related Information section of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(k) Related Information

(1) For more information about this AD, contact Sarah Piccola, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6483; fax: 425–917–6590; email: *sarah.piccola@faa.gov.*

(2) For Boeing service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206- 544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* For Goodrich service information identified in this AD, contact Goodrich Corporation, Aircraft Interior Products, ATTN: Technical Publications, 3414 South Fifth Street, Phoenix, AZ 85040–1169; telephone 602–243–2200; Internet *http://www.goodrich.com/TechPubs.* You may also review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on February 1, 2013.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–02896 Filed 2–7–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. FDA–2013–N–0069]

Medical Devices; Ophthalmic Devices; Classification of the Eyelid Weight

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to classify the eyelid weight into class II (special controls). The eyelid weight may be adhered to the outer skin of the upper eyelid (external eyelid weight) or implanted into the upper eyelid (implantable eyelid weight), and is intended for the gravity assisted treatment of lagophthalmos (incomplete eyelid closure). FDA is also giving notice of its intent to exempt the external eyelid weight device from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act). After considering public comments on the proposed classification, FDA will publish a final regulation classifying this device type.

DATES: Submit either electronic or written comments by May 9, 2013. See section IV of this document for the proposed effective date of a final rule that may issue based on this proposal.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2013–N–0069, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following way:

- *Mail/Hand delivery/Courier (for paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2013–N–0069 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Tina Kiang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2414, Silver Spring, MD 20993–0002, 301–796–6860, *Tina.Kiang@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory and Regulatory Authorities

The FD&C Act (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), and the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of

devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the FD&C Act, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), as ''preamendments devices.'' FDA classifies these devices after the Agency takes the following steps:

- Receives a recommendation from a device classification panel (an FDA advisory committee);
- Publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and
- Publishes a final regulation classifying the device.

FDA has classified most preamendments devices under these procedures.

A person may market a preamendments device that has been classified into class III through premarket notification procedures, without submission of a premarket approval application until FDA publishes a final regulation under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval.

Section 510(m) of the FD&C Act (21 U.S.C. 360(m)) provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act, if the Agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device. FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of the external eyelid weight.

B. Regulatory History of the Device

After the enactment of the Medical Device Amendments of 1976, FDA commenced to identify and classify all preamendments devices, in accordance with section 513(b) of the FD&C Act. In the **Federal Register** of September 2, 1987 (52 FR 33346), FDA classified a total of 109 generic types of ophthalmic devices. The eyelid weight was not identified in this initial effort. FDA has regulated eyelid weights as devices requiring premarket notification (section 510(k) of the FD&C Act). Eyelid weights currently on the market have been determined to be substantially equivalent to devices that were in commercial distribution prior to May 28, 1976.

Consistent with the FD&C Act and the regulations, FDA consulted with the Ophthalmic Devices Panel (the Panel), an FDA advisory committee, regarding the classification of this device type on January 13 and 14, 2000 (Ref. 1).

II. Panel Recommendation

A. Identification

An eyelid weight is a prescription device made of gold, tantalum, platinum, iridium, or surgical grade stainless steel that is rectangular in shape and contoured to the shape of the eye. The device is intended for the gravity assisted treatment of lagophthalmos (incomplete eyelid closure). The external eyelid weight is adhered to the outer skin of the upper eyelid. The implantable eyelid weight is implanted into the upper eyelid.

B. Recommended Classification of the Panel

The Panel recommended that the eyelid weight, both external and implantable, be classified into class II. The Panel also recommended that the external eyelid weight be exempt from premarket notification requirements. The Panel believed that class II classification (with special controls appropriate for the external eyelid weight and special controls appropriate for the implantable eyelid weight) would provide reasonable assurance of the safety and effectiveness of the device.

C. Summary of Reasons To Support the Proposed Panel Recommendation

The Panel considered information from the scientific literature review conducted by FDA, FDA's extensive regulatory experience with the device type, and the Panel members' personal knowledge of and clinical experience with the device type. The Panel also considered the long history of safety and effectiveness of the device, both external and implantable, over many years of clinical use. The Panel recommended that the eyelid weight, external and implantable, be classified into class II because the Panel concluded that special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device type, and that there is sufficient information to establish special controls to provide such assurance for both the external and implantable eyelid weight. The Panel also recommended that the external eyelid weight be exempt from premarket notification requirements, while the implantable eyelid weight would not be exempt from premarket notification.

D. Risks to Health and Special Controls

Based on the Panel's discussion and recommendations and FDA's experience with the device, the risks to health associated with the external eyelid weight and the proposed measures to mitigate these risks are identified in table 1 of this document; the risks to health associated with the implantable eyelid weight and the proposed measures to mitigate these risks are identified in table 2 of this document.

TABLE 1—HEALTH RISKS AND MITIGATION MEASURES FOR THE EXTERNAL EYELID WEIGHT

Identified risk	Mitigation measures
Mild adverse tissue reaction	Biocompatibility testing and labeling.
Magnetic resonance (MR) incompatibility	Nonclinical testing and labeling.
Temporary induced astigmatism (which can result in blurred vision requiring glasses)	Labeling.
Ptosis (droopy eyelid)	Labeling.

Risks associated with the use of the external eyelid weight are related to the placement of the device and the material of which it is composed. Biocompatibility testing will mitigate the risk of mild adverse tissue reaction; nonclinical testing will mitigate the risk of MR incompatibility; labeling will mitigate the risks of mild adverse tissue reaction, temporary induced astigmatism, and ptosis, and communicate potential MR incompatibility.

FDA believes that the following special controls, in addition to general controls, can address the risks to health in table 1 of this document and provide reasonable assurance of safety and effectiveness of the device: (1) Testing demonstrating the biocompatibility of the device; (2) and nonclinical testing evaluating the compatibility of the device in a MR environment. In addition, under 21 CFR 801.109, the sale, distribution, and use of the device are restricted to prescription use.

TABLE 2—HEALTH RISKS AND MITIGATION MEASURES FOR THE IMPLANTABLE EYELID WEIGHT

Identified risk	Mitigation measures
Adverse tissue reaction	Biocompatibility testing and labeling.
Device migration	Biocompatibility testing and labeling.
Extrusion through the eyelid	Biocompatibility testing and labeling.
Infection	Sterility testing.
MR incompatibility	Nonclinical testing and patient labeling.
Induced astigmatism (which can result in blurred vision requiring glasses)	Labeling.
Ptosis	Labeling.

There are additional risks for the implantable eyelid weight, related to the more invasive position of the device, which include infection, device migration, and extrusion through the eyelid. In addition to special controls regarding biocompatibility testing and nonclinical testing for MR compatibility and labeling special controls, FDA is proposing special controls for the implantable eyelid weight addressing sterility and patient labeling. Biocompatibility testing will mitigate the risk of adverse tissue reaction, device migration, and extrusion through the eyelid. Sterility testing will mitigate the risk of infection. Nonclinical testing will mitigate the risk of MR incompatibility. Patient labeling will communicate potential MR incompatibility or the conditions for safe use in an MR environment. Labeling will mitigate the risk of adverse tissue reaction, device migration, extrusion through the eyelid, induced astigmatism, and ptosis.

FDA believes that the following special controls, in addition to general controls, will address the risks to health in table 2 of this document and provide reasonable assurance of safety and effectiveness of the implantable eyelid weight: (1) Testing demonstrating the biocompatibility of the device; (2) testing demonstrating the sterility and shelf life of the device; (3) nonclinical testing evaluating the compatibility of the device in an MR environment; and (4) patient labeling to convey information regarding the safety and compatibility of the device in an MR environment, the conditions under which a patient with the device can be safely scanned, and a mechanism for a healthcare provider to obtain detailed information about MR safety and compatibility if needed. In addition, under § 801.109, the sale, distribution, and use of the device are restricted to prescription use.

III. Proposed Classification and FDA's Findings

To better inform the Agency's proposed classification of the eyelid weight device type as described in this proposed rule, FDA conducted a review of the literature that included relevant scientific and medical information published through 2011 (see representative articles in Refs. 2 through 20). FDA has received no reports of adverse events related to external or implantable eyelid weights. Based upon this updated review of the literature and FDA's continued premarket and postmarket experience with the device type, FDA agrees with the Panel's recommendation that the eyelid weight be classified into class II. FDA believes that special controls for both the external and implantable eyelid weight, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance. FDA also agrees with the Panel's recommendation that premarket notification is not necessary to assure the safety and effectiveness of the external eyelid weight and, therefore, the Agency is giving notice of intent to exempt the external eyelid weight device from premarket notification requirements.

IV. Proposed Effective Date

FDA proposes that any final regulation based on this proposal become effective 30 days after its date of publication in the **Federal Register.**

V. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

A. Introduction

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because classifying these devices as class II will relieve manufacturers of external eyelid weights of the cost of complying with the premarket notification requirements of section 515 of the FD&C Act, and may permit small potential competitors to enter the marketplace by lowering costs, the Agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $139 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

B. Summary

The proposed rule would exempt manufacturers of external eyelid weights from submitting a premarket notification, provided they meet certain special controls. Manufacturers of implantable eyelid weights would still be required to submit a premarket

notification and meet certain special controls. Because the proposed special controls are similar to those in place currently, we do not expect there to be any new costs to society. FDA has concluded that maintaining current controls will place no additional costs on producers and that meeting these special controls provides reasonable assurance that the devices are safe and effective. The special controls are not expected to pose new risks, and thus costs, to public health.

Adopting the proposed rule is expected to benefit society by removing the costs associated with preparing, reviewing, and responding to premarket notifications for manufacturers of external eyelid weights. We estimate the annual costs savings to be $3,438. Over 20 years, the estimated present discounted value of the savings ranges from $28,746, at a 3-percent discount rate, to $20,470 at a 7-percent discount rate.

C. Preliminary Regulatory Impact Analysis

1. Benefits

Adopting the proposed rule would exempt manufacturers of external eyelid weights from submitting premarket notification, resulting in cost savings that are approximately equal to the expenses necessary to prepare, review, and respond to premarket notifications. To calculate these expenses, we multiply the average value of resources necessary to prepare, review, and respond to premarket notifications by the annual reduction in time spent working on these reports [= (the average cost to prepare, review, and respond to a premarket notification) * (annual reduction in number of premarket notifications for external eyelid weights)].

In the past decade, FDA has received one premarket notification related to external eyelid weights. The Agency expects this trend to remain relatively stable over time, and thus projects that implementing the proposed rule would result in an average annual reduction of 0.1 premarket notifications (= 1/10).

The average cost to prepare a premarket notification roughly equals the average number of pages per report multiplied by the average cost to prepare one page. FDA reviewers indicate that, in the last decade the average premarket notification on external eyelid weights is approximately 91 pages long. Blozan and Tucker (Ref. 21) indicates that it costs approximately $500, on average, to prepare a premarket notification that is roughly 24 pages long. This estimate indicates that the average cost to prepare one page is $21 (= $500/24). Updated to 2011 dollars, per page costs roughly equal $37.78 (Ref. 22). Given these measures, we estimate the average cost to prepare a premarket notification is approximately $3,438 (= 91 * $37.78).

The average cost to review one premarket notification was approximately $13,400 in 2004 (Ref. 23). Updated to 2001 dollars, this cost roughly equals $15,695 per premarket notification. Finally, most responses to premarket notifications are 5 pages long. Given that the cost to prepare one page is roughly $37.78, we estimate that the average cost to respond to a premarket notification roughly equals $189 (= 5 * $37.78).

2. Summary and Discussion

The proposed rule is expected to provide modest cost savings to society. We estimate that implementing the proposed rule is expected to result in an average annual cost savings equal to $1932 (= [0.1 reports per year] * [$3438 + $15,695 + $189]). Over 20 years, the estimated present value of the savings is $28,746, at a 3-percent discount rate, and $20,470, at a 7-percent discount rate.

D. Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires Agencies to prepare a regulatory flexibility analysis if a proposed rule would have a significant effect on a substantial number of small businesses, non-profit organizations, local jurisdictions, or other entities. The proposed rule would exempt manufacturers of external eyelid weights from submitting a premarket notification. We expect this exemption to modestly reduce costs associated with gaining premarket approval, and thus certify that the proposed rule would not significantly affect a substantial number of small businesses, non-profit organizations, local jurisdictions, or other entities.

VII. Paperwork Reduction Act of 1995

This proposed rule establishes special controls that refer to currently approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

VIII. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

IX. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov*. (FDA has verified all the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

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List of Subjects in 21 CFR Part 886

Medical devices, Ophthalmic goods and services.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 886 be amended as follows:

PART 886—OPHTHALMIC DEVICES

■ 1. The authority citation for 21 CFR part 886 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 886.5700 is added to subpart F to read as follows:

§ 886.5700 Eyelid weight.

(a) *Identification.* An eyelid weight is a prescription device made of gold, tantalum, platinum, iridium, or surgical grade stainless steel that is rectangular in shape and contoured to the shape of the eye. The device is intended for the gravity assisted treatment of lagophthalmos (incomplete eyelid closure).

(1) The external eyelid weight is adhered to the outer skin of the upper eyelid.

(2) The implantable eyelid weight is implanted into the upper eyelid.

(b) *Classification.* (1) Class II (special controls) for the external eyelid weight. The external eyelid weight is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9. The special controls for the external eyelid weight are:

(i) Testing demonstrating the biocompatibility of the device;

(ii) Nonclinical testing evaluating the compatibility of the device in a magnetic resonance (MR) environment;

(iii) Labeling to include all information required for the safe and effective use of the device as outlined in § 801.109(c) of this chapter, including specific instructions regarding the proper placement, sizing, and removal of the device; and

(2) Class II (special controls) for the implantable eyelid weight. The special controls for the implantable eyelid weight are:

(i) Testing demonstrating the biocompatibility of the device;

(ii) Testing demonstrating the sterility and shelf life of the device;

(iii) Nonclinical testing evaluating the compatibility of the device in an MR environment.

(iv) Patient labeling to convey information regarding the safety and compatibility of the device in an MR environment, the conditions under which a patient with the device can be safely scanned, and a mechanism for a healthcare provider to obtain detailed information about MR safety and compatibility if needed.

Dated: February 1, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–02862 Filed 2–7–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 571

[BOP–1090–P]

RIN 1120–AA85

Designation of Offenses

AGENCY: Federal Bureau of Prisons, Department of Justice.

ACTION: Proposed rule.

SUMMARY: The Bureau of Prisons (Bureau) proposes to remove rules which designate various offenses as sexual offenses for purposes of U.S. Code because that provision, which necessitated regulations, has been repealed in relevant part.

DATES: Comments are due by April 9, 2013.

FOR FURTHER INFORMATION CONTACT: Sarah Qureshi, Office of General Counsel, Bureau of Prisons, phone (202) 307–2105.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record and made available for public inspection online at *www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your

name, address, etc.) as part of your comment, but do not want it to be posted online, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also locate all the personal identifying information you do not want posted online in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment but do not want it to be posted online, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment contains so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted on *www.regulations.gov.*

Personal identifying information identified and located as set forth above will be placed in the agency's public docket file, but not posted online. Confidential business information identified and located as set forth above will not be placed in the public docket file. If you wish to inspect the agency's public docket file in person by appointment, please see the ''For Additional Information'' paragraph.

Proposed Rule

The Bureau proposes to remove rules which designate various offenses as sexual offenses for purposes of 18 U.S.C. 4042(c) because that provision, which necessitated regulations, has been repealed in relevant part. The Bureau published an interim rule on this subject on December 16, 1998 (63 FR 69386) (1998 interim rule). When this proposed rule is finalized, it will result in the retraction/deletion of the 1998 interim rule.

Previously, section 4042(c) of Title 18, United States Code, effective November 26, 1998, provided for notification of sex offender release and certain related functions to facilitate effective sex offender registration and tracking. Notifications were required to be made for persons convicted of the federal offenses noted in subsection (c)(4)(A) through (D). Subsection (c)(4)(E) authorized the Attorney General to designate other offenses as sexual offenses for purposes of subsection (c). The Attorney General delegated this authority to the Director of the Bureau of Prisons. (*See* 63 FR 69386, December 16, 1998.)

The 1998 interim rule designated additional offenses which are to be considered sexual offenses for purposes of 18 U.S.C. 4042(c). These additional designations, listed in current § 571.72, include state sexual offenses, District of Columbia Code sexual offenses, and certain Uniform Code of Military Justice offenses.

The current regulations, therefore, were specifically promulgated in accordance with language in § 4042(c)(4)(E) providing that offenses in addition to those specifically enumerated at 4042(c)(4)(A)–(D) may be ''designated by the Attorney General as a sexual offense for the purposes of this subsection.''

However, 18 U.S.C. 4042(c)(4) was repealed by the Sex Offender Registration and Notification Act (SORNA), which is Title I of the Adam Walsh Child Protection and Safety Act of 2006 (Pub. L. 109–248). Because the revised 18 U.S.C. 4042(c) requires release notice for persons required to register under SORNA, the Bureau no longer needs to separately designate sexual offenses in addition to those set forth by the statute. The offenses previously listed in the regulation are generally incorporated in SORNA's comprehensive list of covered offenses, thereby rendering the Bureau's current regulations in subpart H of 28 CFR part 571 unnecessary. We therefore now propose to remove and reserve 28 CFR part 571, subpart H.

Executive Order 12866

This regulation has been drafted and reviewed in accordance with Executive Order 12866, ''Regulatory Planning and Review'', section 1(b), Principles of Regulation. The Director, Bureau of Prisons has determined that this rule is not a ''significant regulatory action'' under Executive Order 12866, section 3(f), and accordingly this rule has not been reviewed by the Office of Management and Budget.

Executive Order 13132

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. Under Executive Order 13132, this rule does not have sufficient federalism implications for which we would prepare a Federalism Assessment.

Regulatory Flexibility Act

The Director of the Bureau of Prisons, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), reviewed this regulation. By approving it, the Director certifies that it will not have a significant economic impact upon a substantial number of small entities because: this rule is about the correctional management of offenders committed to the custody of the Attorney General or the Director of the Bureau of Prisons, and its economic impact is limited to the Bureau's appropriated funds.

Unfunded Mandates Reform Act of 1995

This rule will not cause State, local and tribal governments, or the private sector, to spend $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. We do not need to take action under the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 28 CFR Part 571

Prisoners.

Charles E. Samuels, Jr.,
Director, Bureau of Prisons.

Under rulemaking authority vested in the Attorney General in 5 U.S.C. 301; 28 U.S.C. 509, 510 and delegated to the Director, Bureau of Prisons in 28 CFR § 0.96, we propose to amend 28 CFR part 571 as set forth below.

SUBCHAPTER D—COMMUNITY PROGRAMS AND RELEASE

PART 571—RELEASE FROM CUSTODY

■ 1. The authority citation for Part 571 continues to read as follows:

Authority: 5 U.S.C. 301; 18 U.S.C. 3565, 3568–3569 (Repealed in part as to offenses committed on or after November 1, 1987), 3582, 3621, 3622, 3624, 4001, 4042, 4081, 4082 (Repealed in part as to offenses committed on or after November 1, 1987), 4161–4166 and 4201–4218 (Repealed as to offenses committed on or after November 1, 1987), 5006–5024 (Repealed October 12, 1984 as to offenses committed after that date), 5031–5042; 28 U.S.C. 509, 510; U.S. Const., Art. II, Sec. 2; 28 CFR 0.95–0.99, 1.1–1.10.

Subpart H [Removed and Reserved]

■ 2. Subpart H, Designation of Offenses for Purposes of 18 U.S.C. 4042(c) is removed and reserved.

[FR Doc. 2013–02765 Filed 2–7–13; 8:45 am]

BILLING CODE 4410–05–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2013–0013; FRL–9777–6]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Removal of the Mount Saint Mary's College 1979 Consent Order

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the State of Maryland Department of the Environment (MDE) for the purpose of removing Mount Saint Mary's College 1979 Consent Order from the Maryland SIP. In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because EPA views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rulemaking action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this rulemaking action should do so at this time.

DATES: Comments must be received in writing by March 11, 2013.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2013–0013 by one of the following methods:

A. *www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. *Email: mastro.donna@epa.gov.*

C. *Mail:* EPA–R03–OAR–2013–0013, Donna Mastro, Acting Associate Director, Air Protection Division, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2013–0013. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *ww.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland 21230.

FOR FURTHER INFORMATION CONTACT: Maria Pino, Air Protection Division, Project officer, (215) 814–2181, or by email at *pino.maria@epa.gov.*

SUPPLEMENTARY INFORMATION: For further information, please see the information provided in the direct final action, with the same title, that is located in the ''Rules and Regulations'' section of this **Federal Register** publication.

Dated: January 25, 2013.

W.C. Early,

Acting Regional Administrator, Region III.

[FR Doc. 2013–02814 Filed 2–7–13; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket: CDC–2012–0010]

42 CFR Part 73

Influenza Viruses Containing the Hemagglutinin From the Goose/Guangdong/1/96 Lineage

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for information; reopening of comment period.

SUMMARY: With this notice, the Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) announces the re-opening of a public comment period for a request for information and comment published on October 17, 2012. The request for information sought information and comments from the public regarding whether highly pathogenic avian influenza (HPAI) H5N1 viruses that contain a hemagglutinin (HA) from the Goose/Guangdong/1/96 lineage, and their potential to pose a severe threat to public health and safety. The comment period closed on December 17, 2012. We are reopening the comment period to allow interested persons additional time to prepare and submit comments.

DATES: Written or electronic comments must be received on or before March 11, 2013.

ADDRESSES: You may submit comments, identified by Docket Number CDC–2012–0010, by any of the following methods

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Road NE., Mailstop A–46,

Atlanta, Georgia 30333, ATTN: Docket No. CDC–2012–0010.

Instructions: All submissions received must include the agency name and RIN for this rulemaking. All relevant comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket Access: For access to the docket to read background documents or comments received or to download an electronic version of the NPRM, go to *http://www.regulations.gov.* Comments will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m. at 1600 Clifton Road NE., Atlanta, GA, 30333. Please call ahead to 1–866–694–4867 and ask for a representative in the Division of Select Agents and Toxins to schedule your visit. Our general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet as they are received and without change.

FOR FURTHER INFORMATION CONTACT: Robbin Weyant, Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS A–46, Atlanta, Georgia 30333. Telephone: (404) 718–2000.

SUPPLEMENTARY INFORMATION: On October 17, 2012, the Centers for Disease Control and Prevention(CDC), located within the Department of Health and Human Services (HHS) published a request for information and comment in the **Federal Register** (77 FR 63783) to obtain information and comments from the public to questions concerning highly pathogenic avian influenza (HPAI) H5N1 viruses that contain a hemagglutinin (HA) from the Goose/Guangdong/1/96 lineage, and their potential to pose a severe threat to public health and safety. The comment period closed on December 17, 2012. We have re-opened the comment period to allow interested persons additional time to prepare and submit comments. We will also accept comments received between December 18, 2012 (the day after the close of the original comment period) and the date of this notice.

Dated: February 4, 2013.

Kathleen Sebelius,

Secretary.

[FR Doc. 2013–02828 Filed 2–7–13; 8:45 am]

BILLING CODE 4163–18–P

Notices

Federal Register
Vol. 78, No. 27
Friday, February 8, 2013

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

February 4, 2013.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Rural Business-Cooperative Service

Title: Renewable Energy Systems and Energy Efficiency Improvements under the Rural Energy for America Program.

OMB Control Number: 0570–0050.

Summary of Collection: This program is authorized under the Food, Conservation, and Energy Act of 2008 (Act) that established the Rural Energy for America Program (REAP) under Title IX, Section 9007. The Act requires the Secretary of Agriculture to provide grants and/or guaranteed loans for several types of projects, including grants, loan guarantees, and grants and loan guarantees (combined funding) to agricultural producers and rural small businesses to purchase renewable energy systems and make energy efficiency improvements. REAP is designed to help agricultural producers and rural small business reduce energy cost and consumption, develop new income streams, and help meet the nation's critical energy needs. Applicants wishing to apply for the grant or guaranteed loans will have to submit applications along with specified documents to the State Rural Energy Coordinator.

Need and Use of the Information: RBS will use the collected information to determine applicant eligibility, to determine project eligibility and feasibility, ensure compliance with applicable regulations, and to ensure that grantees/borrowers operate on a sound basis and use funds for authorized purposes. Without this collection of information RBS would be unable to meet the requirements of the Act and effectively administer the program.

Description of Respondents: Farmers, Ranchers, and Business or other for-profit.

Number of Respondents: 3,634.

Frequency of Responses: Annually.

Total Burden Hours: 310,184.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 2013–02809 Filed 2–7–13; 8:45 am]

BILLING CODE 3410–XT–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

February 4, 2013.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food and Nutrition Service

Title: Supplemental Form for Collecting Taxpayer Identifying Numbers.

OMB Control Number: 0584–0501.

Summary of Collection: Section 31001(y) of the Debt Collection

Improvement Act of 1996 (Public Law 104–134) requires all Federal agencies to obtain taxpayer identifying number (TINs) from all individuals and entities they enter into a direct payment agreement with to furnish the TIN whenever a request for payment is submitted to Federal payment officials. A taxpayer identifying number can be either a Social Security Number or an Employer Identification Number.

Need and Use of the Information: The Food and Nutrition Service (FNS) will collect information using form FNS–711, ''Supplemental Form for Collecting Taxpayer Identifying Numbers'' from individuals and entities receiving payments directly from the agency under any of the various nutrition and nutrition education programs administered by the Agency. The information is collected at the time of program application, and is only collected once unless an entity renews its application or reapplies for program participation. If the information were not collected, FNS would be unable to include taxpayer identifying numbers with each certified request for payment.

Description of Respondents: Business or other for-profit; Individuals or households; Not-for-profit institutions.

Number of Respondents: 800.

Frequency of Responses: Report: On occasion; Other (at time of app.).

Total Burden Hours: 66.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2013–02807 Filed 2–7–13; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Dairyland Power Cooperative: CapX 2020 Hampton-Rochester-La Crosse 345-kV Transmission Line Proposal

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of Availability of a Record of Decision.

SUMMARY: The Rural Utilities Service (RUS) has issued a Record of Decision (ROD) for the Environmental Impact Statement (EIS) related to providing financial assistance to the Dairyland Power Cooperative (Dairyland) for its share in the construction of a proposed 345-kilovolt (kV) transmission line and associated infrastructure between Hampton, Minnesota and the La Crosse area in Wisconsin (Proposal). The Administrator of RUS has signed the ROD, which was effective upon signing. The EIS was prepared pursuant to the National Environmental Policy Act (NEPA) (U.S.C. 4231 et seq.) and in accordance with the Council on Environmental Quality's (CEQ) regulations for implementing the procedural provisions of NEPA (40 CFR Parts 1500–1508) and RUS' Environmental Policies and Procedures (7 CFR part 1794).

ADDRESSES: To obtain copies of the ROD or for further information, contact: Stephanie Strength, Environmental Protection Specialist, USDA, Rural Utilities Service, 1400 Independence Avenue SW., Room 2244, Stop 1571, Washington, DC 20250–1571, or email *stephanie.strength@wdc.usda.gov.* The ROD is also available at RUS' Web site at *http://www.rurdev.usda.gov/UWP-CapX2020-Hampton-Rochester-LaCrosse.html.*

SUPPLEMENTARY INFORMATION: As the lead federal agency, and as part of its broad environmental review process, RUS must take into account the effect of the Proposal on historic properties in accordance with Section 106 of the National Historic Preservation Act (16 U.S.C. 470f) and its implementing regulation ''Protection of Historic Properties'' (36 CFR part 800). Pursuant to 36 CFR 800.2(d)(3), RUS used its procedures for public involvement under NEPA, in part, to meet its responsibilities to solicit and consider the views of the public and other interested parties during the Section 106 review process. Accordingly, comments submitted in the EIS process also informed RUS's decision making in the Section 106 review process.

Dairyland is participating in the proposal with a number of other utilities. The other participants include Xcel Energy [comprised of Northern States Power Company, a Minnesota Corporation (NSPM), and Northern States Power Company, a Wisconsin Corporation (NSPW)], Southern Minnesota Municipal Power Agency (SMMPA), Rochester Public Utilities (RPU), and WPPI Energy, Inc. (WPPI)]. The purpose of the proposal is to: (1) Improve community reliability of the transmission system in Rochester, Winona, La Crosse, and the surrounding areas, which include areas Dairyland currently provides electrical service; (2) improve the regional reliability of the transmission system; and (3) increase generation outlet capacity.

The U.S. Army Corps of Engineers (USACE) and the U.S. Fish and Wildlife Service (USFWS) participated in the EIS as cooperating agencies, with RUS as the lead federal agency. The USACE and the USFWS will each issue its own ROD as necessary. The proposal includes construction and operation of a 345-kV transmission line and associated infrastructure, two 161-kV transmission lines in the vicinity of Rochester, Minnesota, and two new and three expanded substations, with a total transmission line length of approximately 171 miles. Counties through which the proposal will pass include Dakota, Goodhue, Wabasha, and Olmsted in Minnesota, and La Crosse, Trempealeau, and Buffalo in Wisconsin.

The decision documented in RUS' ROD is that RUS agrees to consider, subject to loan approval, financing Dairyland's share in the proposal. Details regarding RUS' regulatory authority, rationale for the decision, and compliance with applicable regulations are included in the ROD.

RUS published its Notice of Availability (NOA) for the Draft EIS in the **Federal Register** on December 16, 2011 (76 FR 78235–78236), and in newspapers of general circulation within the proposal's area of environmental impact. The U.S. Environmental Protection Agency (USEPA) published its notice of receipt of the Draft EIS in the **Federal Register** on December 16, 2011 (76 FR 78235–78236). The comment period for the Draft EIS was extended from 45 to 60 days and ended on February 13, 2012. Public hearings to receive comments on the Draft EIS were held from January 9 to 13, 2012, in Alma and Galesville, Wisconsin; Wanamingo, Cannon Falls, and Plainview, Minnesota. All comments received on the Draft EIS were addressed in the Final EIS. RUS published its NOA of the Final EIS in the **Federal Register** on July 13, 2012 (77 FR 41369–41370), and in newspapers of general circulation within the Proposal's area of environmental impact. USEPA published its notice of receipt of the Final EIS in the **Federal Register** on July 20, 2012 (77 FR 42727–42728). The 30-day comment period ended on August 20, 2012. Comments received on the Final EIS were addressed in the ROD. After considering alternatives to meet the purpose and need of the proposal, Dairyland identified participation in construction of the proposal as its best course of action. A number of alternatives to meet the purpose and need were considered, but not studied in detail, including demand side management, use of existing generation and transmission, new generation, decentralized generation systems, undergrounding of the transmission line, and a number of route alternatives.

Among the alternatives addressed in detail in the EIS is the No Action alternative, under which the proposal

would not be undertaken, and a number of route alternatives identified and considered in the EISs prepared for the proposal by the States of Minnesota and Wisconsin.

Based on an evaluation of the information and impact analyses presented in the EIS, RUS finds that the evaluation of reasonable alternatives is consistent with NEPA and RUS Environmental Policies and Procedures. Details regarding RUS' regulatory authority, rationale for the decision, and compliance with applicable regulations are included in the ROD. Because the proposal may involve action in floodplains or wetlands, this Notice also serves as a final notice of action in floodplains and wetlands (in accordance with Executive Orders 11988 and 11990).

This ROD is not a decision on Dairyland's loan application and therefore not an approval of the expenditure of federal funds. This notice of the ROD concludes RUS' environmental review process in accordance with NEPA and RUS' Environmental Policies and Procedures (7 CFR 1794). The ultimate decision as to loan approval depends upon the conclusion of this environmental review process plus financial and engineering analyses. Issuance of the ROD will allow these reviews to proceed.

Dated: January 11, 2013.

John Charles Padalino,

Acting Administrator, Rural Utilities Service.

[FR Doc. 2013–02805 Filed 2–7–13; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Bureau of Industry And Security

Order Renewing Order Temporarily Denying Export Privileges and Making That Temporary Denial of Export Privilges Applicable to an Additional Related Person

Mahan Airways, Mahan Tower, No. 21, Azadegan St., M.A. Jenah Exp. Way, Tehran, Iran

Zarand Aviation, a/k/a GIE Zarand Aviation, 42 Avenue Montaigne, 75008 Paris, France and 112 Avenue Kleber, 75116 Paris, France

Gatewick LLC, a/k/a Gatewick Freight & Cargo Services, a/k/a/Gatewick Aviation Services, G#22 Dubai Airport Free Zone, P.O. Box 393754, Dubai, United Arab Emirates and P.O. Box 52404, Dubai, United Arab Emirates and Mohamed Abdulla Alqaz Building, Al Maktoum Street, Al Rigga, Dubai, United Arab Emirates;

Pejman Mahmood Kosarayanifard, a/k/a Kosarian Fard, P.O. Box 52404, Dubai, United Arab Emirates; Mahmoud Amini, G#22 Dubai Airport Free Zone, P.O. Box 393754, Dubai, United Arab Emirates and P.O. Box 52404, Dubai, United Arab Emirates and Mohamed Abdulla Alqaz Building, Al Maktoum Street, Al Rigga, Dubai, United Arab Emirates

Kerman Aviation, a/k/a GIE Kerman Aviation, 42 Avenue Montaigne 75008, Paris, France

Sirjanco Trading. P.O. Box 8709, Dubai, United Arab Emirates

Ali Eslamian, 4th Floor, 33 Cavendish Square, London, W1G0PW, United Kingdom and 2 Bentinck Close, Prince Albert Road St. Johns Wood, London NW87RY, United Kingdom

Mahan Air General Trading LLC, 19th Floor Al Moosa Tower One Sheik Zayed Road, Dubai 40594, United Arab Emirates

Skyco (UK) Ltd., 4th Floor, 33 Cavendish Square, London, W1G 0PV, United Kingdom

Equipco (UK) Ltd., 2 Bentinck Close, Prince Albert Road, London, NW8 7RY, United Kingdom

Mehdi Bahrami, Mahan Airways—Istanbul Office, Cumhuriye Cad. Sibil Apt No: 101 D:6, 34374 Emadad, Sisli Istanbul, Turkey

Pursuant to Section 766.24 of the Export Administration Regulations, 15 CFR parts 730–774 (2012) (''EAR'' or the ''Regulations''), I hereby grant the request of the Office of Export Enforcement (''OEE'') to renew the August 9, 2012 Order Temporarily Denying the Export Privileges of Mahan Airways, Zarand Aviation, Gatewick LLC, Pejman Mahmood Kosarayanifard, Mahmoud Amini, Kerman Aviation, Sirjanco Trading LLC, Ali Eslamian, Mahan Air General Trading LLC, Skyco (UK) Ltd., and Equipco (UK) Ltd. I find that renewal of the Temporary Denial Order (''TDO'') is necessary in the public interest to prevent an imminent violation of the EAR. Additionally, pursuant to Section 766.23 of the Regulations, including the provisions of notice and an opportunity to respond, I find it necessary to add the following person as a related person in order to prevent evasion of the TDO:

Mehdi Bahrami, Mahan Airways—Istanbul Office, Cumhuriye Cad. Sibil Apt No: 101 D:6, 34374 Emadad, Sisli Istanbul, Turkey

I. Procedural History

On March 17, 2008, Darryl W. Jackson, the then-Assistant Secretary of Commerce for Export Enforcement (''Assistant Secretary''), signed a TDO denying Mahan Airways' export privileges for a period of 180 days on the grounds that its issuance was necessary in the public interest to prevent an imminent violation of the Regulations. The TDO also named as denied persons Blue Airways, of Yerevan, Armenia (''Blue Airways of Armenia''), as well as the ''Balli Group Respondents,'' namely, Balli Group PLC, Balli Aviation, Balli Holdings, Vahid Alaghband, Hassan Alaghband, Blue Sky One Ltd., Blue Sky Two Ltd., Blue Sky Three Ltd., Blue Sky Four Ltd., Blue Sky Five Ltd., and Blue Sky Six Ltd., all of the United Kingdom. The TDO was issued *ex parte* pursuant to Section 766.24(a), and went into effect on March 21, 2008, the date it was published in the **Federal Register**.

The TDO subsequently has been renewed in accordance with Section 766.24(d), including most recently on August 9, 2012, with modifications and the additions of related persons having been made to the TDO during 2010, 2011, and most recently on April 9, 2012.[1] As of March 9, 2010, the Balli Group Respondents and Blue Airways were no longer subject to the TDO. As part of the February 25, 2011 TDO renewal, Gatwick LLC, Mahmoud Amini, and Pejman Mahmood Kasarayanifard (''Kosarian Fard'') were added as related persons in accordance with Section 766.23 of the Regulations. On July 1, 2011, the TDO was modified by adding Zarand Aviation as a respondent in order to prevent an imminent violation. Specifically, Zarand Aviation owned an Airbus A310 subject to the Regulations that was being operated for the benefit of Mahan Airways in violation of both the TDO and the Regulations. As part of the August 24, 2011 renewal, Kerman Aviation, Sirjanco Trading LLC, and Ali Eslamian were added to the TDO as related persons. Mahan Air General Trading LLC, Skyco (UK) Ltd., and Equipco (UK) Ltd. were added as related persons on April 9, 2012.

On January 15, 2013, BIS, through its Office of Export Enforcement (''OEE''), submitted a written request for renewal of the TDO. The current TDO dated August 9, 2012, will expire on February 4, 2013, unless renewed on or before that date. Notice of the renewal request was provided to Mahan Airways and Zarand Aviation by delivery of a copy of the request in accordance with Sections 766.5 and 766.24(d) of the Regulations. No opposition to any aspect of the renewal of the TDO has been received from either Mahan Airways or Zarand Aviation. Furthermore, no appeal of the related

[1] The August 9, 2012 Order was published in the **Federal Register** on August 15, 2012. *See* 77 F.R. 48,960 (Aug. 15, 2012. The TDO previously had been renewed on September 17, 2008, March 16, 2009, September 11, 2009, March 9, 2010, September 3, 2010, February 25, 2011, August 24, 2011, and February 15, 2012. The August 24, 2011 renewal followed the modification of the TDO on July 1, 2011, which added Zarand Aviation as a respondent. Each renewal or modification order was published in the **Federal Register**.

person determinations I made as part of the September 3, 2010, February 25, 2011, August 24, 2011, and April 9, 2012 renewal or modification orders has been made by Gatewick LLC, Kosarian Fard, Mahmoud Amini, Kerman Aviation, Sirjanco Trading LLC, Ali Eslamian, Mahan Air General Trading LLC, Skyco (UK) Ltd., or Equipco (UK) Ltd.[2]

II. Renewal of the TDO

A. Legal Standard

Pursuant to Section 766.24, BIS may issue or renew an order temporarily denying a respondent's export privileges upon a showing that the order is necessary in the public interest to prevent an ''imminent violation'' of the Regulations. 15 CFR 766.24(b)(1) and 776.24(d). ''A violation may be 'imminent' either in time or degree of likelihood.'' 15 CFR 766.24(b)(3). BIS may show ''either that a violation is about to occur, or that the general circumstances of the matter under investigation or case under criminal or administrative charges demonstrate a likelihood of future violations.'' *Id.* As to the likelihood of future violations, BIS may show that ''the violation under investigation or charges is significant, deliberate, covert and/or likely to occur again, rather than technical or negligent [.]'' *Id.* A ''lack of information establishing the precise time a violation may occur does not preclude a finding that a violation is imminent, so long as there is sufficient reason to believe the likelihood of a violation.'' *Id.*

B. The TDO and BIS's Request for Renewal

OEE's request for renewal is based upon the facts underlying the issuance of the initial TDO and the TDO renewals in this matter and the evidence developed over the course of this investigation indicating a blatant disregard of U.S. export controls and the TDO. The initial TDO was issued as a result of evidence that showed that Mahan Airways and other parties engaged in conduct prohibited by the EAR by knowingly re-exporting to Iran three U.S.-origin aircraft, specifically Boeing 747s (''Aircraft 1–3''), items subject to the EAR and classified under Export Control Classification Number (''ECCN'') 9A991.b, without the required U.S. Government authorization. Further evidence submitted by BIS indicated that Mahan Airways was involved in the attempted re-export of three additional U.S.-origin Boeing 747s (''Aircraft 4–6'') to Iran.

As discussed in the September 17, 2008 TDO Renewal Order, evidence presented by BIS indicated that Aircraft 1–3 continued to be flown on Mahan Airways' routes after issuance of the TDO, in violation of the Regulations and the TDO itself.[3] It also showed that Aircraft 1–3 had been flown in further violation of the Regulations and the TDO on the routes of Iran Air, an Iranian Government airline. Moreover, as discussed in the March 16, 2009, September 11, 2009 and March 9, 2010 Renewal Orders, Mahan Airways registered Aircraft 1–3 in Iran, obtained Iranian tail numbers for them (including EP–MNA and EP–MNB), and continued to operate at least two of them in violation of the Regulations and the TDO,[4] while also committing an additional knowing and willful violation of the Regulations and the TDO when it negotiated for and acquired an additional U.S.-origin aircraft. The additional acquired aircraft was an MD–82 aircraft, which subsequently was painted in Mahan Airways' livery and flown on multiple Mahan Airways' routes under tail number TC–TUA.

The March 9, 2010 Renewal Order also noted that a court in the United Kingdom (''U.K.'') had found Mahan Airways in contempt of court on February 1, 2010, for failing to comply with that court's December 21, 2009 and January 12, 2010 orders compelling Mahan Airways to remove the Boeing 747s from Iran and ground them in the Netherlands. Mahan Airways and the Balli Group Respondents had been litigating before the U.K. court concerning ownership and control of Aircraft 1–3. In a letter to the U.K. court dated January 12, 2010, Mahan Airways' Chairman indicated, *inter alia,* that Mahan Airways opposes U.S. Government actions against Iran, that it continued to operate the aircraft on its routes in and out of Tehran (and had 158,000 ''forward bookings'' for these aircraft), and that it wished to continue to do so and would pay damages if required by that court, rather than ground the aircraft.

The September 3, 2010 Renewal Order discussed the fact that Mahan Airways' violations of the TDO extended beyond operating U.S.-origin aircraft in violation of the TDO and attempting to acquire additional U.S.-origin aircraft. In February 2009, while subject to the TDO, Mahan Airways participated in the export of computer motherboards, items subject to the Regulations and designated as EAR99, from the United States to Iran, via the United Arab Emirates (''UAE''), in violation of both the TDO and the Regulations, by transporting and/or forwarding the computer motherboards from the UAE to Iran. Mahan Airways' violations were facilitated by Gatewick LLC, which not only participated in the transaction, but also has stated to BIS that it is Mahan Airways' sole booking agent for cargo and freight forwarding services in the UAE.

Moreover, in a January 24, 2011 filing in the U.K. court, Mahan Airways asserted that Aircraft 1–3 were not being used, but stated in pertinent part that the aircraft were being maintained in Iran especially ''in an airworthy condition'' and that, depending on the outcome of its U.K. court appeal, the aircraft ''could immediately go back into service * * *;. on international routes into and out of Iran.'' Mahan Airways' January 24, 2011 submission to U.K. Court of Appeal, at p. 25, ¶¶ 108, 110. This clearly stated intent, both on its own and in conjunction with Mahan Airways' prior misconduct and statements, demonstrated the need to renew the TDO in order to prevent imminent future violations.[5]

More recently, as noted in the July 1, 2011 and August 24, 2011 Orders, Mahan Airways has continued to evade U.S. export control laws by operating two Airbus A310 aircraft[6] bearing Mahan Airways' livery, colors and logo, on flights into and out of Iran. The aircraft are owned, respectively, by Zarand Aviation and Kerman Aviation, entities whose corporate registrations both list Mahan Air General Trading as a member of their Groupement D'interet Economique (''Economic Interest Group'').[7]

At the time of the July 1, 2011 and August 24, 2011 Orders, these Airbus

[2] A party named or added as a related person may not oppose the issuance or renewal of the underlying temporary denial order, but may file an appeal of the related person determination in accordance with Section 766.23(c).

[3] Engaging in conduct prohibited by a denial order violates the Regulations. 15 CFR 764.2(a) and (k).

[4] The third Boeing 747 appeared to have undergone significant service maintenance and may not have been operational at the time of the March 9, 2010 Renewal Order.

[5] Two of these three 747s have since been removed from Iran and are no longer in Mahan Airways' possession. The third remains in Iran under Mahan's control.

[6] The Airbus A310s are powered with U.S.-origin engines. The engines are subject to the EAR and classified under Export Control Classification (''ECCN'') 9A991.d. The Airbus A310s contain controlled U.S.-origin items valued at more than 10 percent of the total value of the aircraft and as a result are subject to the EAR. They are classified under ECCN 9A991.b. The reexport of these aircraft to Iran requires U.S. Government authorization pursuant to Section 746.7 of the Regulations.

[7] Kerman Aviation's corporate registration also lists Mahan Aviation Services Company as an additional member of its Economic Interest Group.

A310s were registered in France, with tail numbers F–OJHH and F–OJHI, respectively. OEE subsequently presented evidence that after the August 24, 2011 renewal, Mahan Airways and Zarand Aviation worked in concert, along with Kerman Aviation, to de-register the two Airbus A310 aircraft in France and to register both aircraft in Iran (with, respectively, Iranian tail numbers EP–MHH and EP–MHI). It was determined subsequent to the February 15, 2012 renewal that the registration switch for these A310s was cancelled; however, both aircraft continued to actively fly for Mahan Airways under the original French tail numbers.

The August 2012 Renewal Order found that Mahan Airways had acquired an additional Airbus A310 aircraft (Manufacturer Serial Number 499) with the Iranian registered tail number EP–VIP, in violation of the TDO.[8] Open source information submitted by OEE indicated that an A310 with a German Air Force designation of 10–22 had served as the German ''presidential'' aircraft and had been sold in Germany as surplus in late 2011, then re-sold shortly thereafter to what was identified as an Eastern European investment group, and then re-sold again and transported to Mahan Airways in Iran via the Ukraine. This acquisition and reexport by and/or for Mahan Airways violated the TDO and the Regulations.

The August 2012 Renewal Order also discussed additional evidence relating to efforts by related persons, including Ali Eslamian, to procure aircraft and aircraft parts for Mahan Airways in violation of the TDO and the Regulations. OEE's January 15, 2013 renewal request similarly presents further evidence of continued and additional violations, including continuing efforts by Mahan Airways and others persons acting in concert with Mahan to procure U.S.-origin engines and other aircraft parts subject to the Regulations.

OEE's current submission includes evidence showing that in July 2012, a Turkish company (''Turkish Company No. 1'') purchased a U.S.-origin Turbojet aircraft engine (Serial Number 517–621) for Mahan Airways from a U.S company. To prevent the engine from being delivered to Mahan Airways, OEE issued a redelivery order to the freight forwarder on July 25, 2012, in accordance with Section 758.8 of the Regulations.[9] The freight forwarder returned the item to the United States from Turkey. In or about July and August 2012, Turkish Company No. 1 attempted to acquire for reexport to Mahan another U.S.-origin aircraft engine (Serial number 517–738), which had previously been exported from the United States. OEE promptly issued a redelivery order for this engine to Turkish Company No. 1 on July 30, 2012. Subsequent to the August 2012 Renewal Order, the owner of that engine cancelled the sale and retained the engine. In September 2012, OEE was alerted by a U.S. exporter that another Turkish company (''Turkish Company No. 2'') was attempting to purchase aircraft spare parts intended for re-export by Turkish Company No. 2 to Mahan Airways.

In addition to these similar, repeated attempts to evade the TDO and obtain U.S.-origin aircraft engines and parts, Mahan Airways also has continued to operate multiple aircraft in violation of the TDO and the Regulations. The two A310s that bear the tail numbers F–OJHH and F–OJHI and are owned by Zarand Aviation and Kerman Aviation, respectively, remain listed in active operation in Mahan Airways' fleet, and other recent open source information indicates that these aircraft have continued to be flown in and out of Iran. On September 19, 2012, both aircraft were designated as Specially Designated Global Terrorists (SDGT) by the U.S. Department of the Treasury's Office of Foreign Assets Control (''OFAC'') pursuant to Executive Order 13324. *See http://www.treasury.gov/resource-center/sanctions/OFAC-Enforcement/pages/20120919.aspx.*[10]

A U.S.-origin Boeing 747 (MSN 23480) bearing the Iranian tail number EP–MNE also remains listed in active operation in Mahan Airways' fleet. Open source information indicates that this 747, which also was designated by OFAC as a SDGT on September 19, 2012, is painted in the livery and logo of Mahan Airways, has been flown between Iran and Syria, and is suspected of ferrying weapons and/or other equipment to the Syrian Government from Iran's Islamic Revolutionary Guard Corps. The unlicensed reexport of this aircraft to Iran and Syria not only violates both the TDO and the Regulations, but also further damages U.S. national security and foreign policy interests to the extent this misconduct has provided weapons or other support to the Assad regime in Syria or advanced Iranian interests there or in the region.

C. Findings

Under the applicable standard set forth in Section 766.24 of the Regulations and my review of the entire record, I find that the evidence presented by BIS convincingly demonstrates that Mahan Airways has continually violated the EAR and the TDO, that such knowing violations have been significant, deliberate and covert, and that there is a likelihood of future violations. Additionally, Zarand Aviation's Airbus A310 continues to be operated in violation of the TDO. Therefore, renewal of the TDO is necessary to prevent imminent violation of the EAR and to give notice to companies and individuals in the United States and abroad that they should continue to cease dealing with Mahan Airways, Zarand Aviation, and the other denied persons under the TDO in export transactions involving items subject to the EAR.

III. Addition of Related Person

Pursuant to Sections 766.23 and 766.24(c) of the Regulations, OEE has requested that Mehdi Bahrami be added to the TDO as related person to Mahan Airways, in order to prevent evasion of the TDO.

A. Legal Standard

Section 766.23 of the Regulations provides that ''[i]n order to prevent evasion, certain types of orders under this part may be made applicable not only to the respondent, but also to other persons then or thereafter related to the respondent by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business. Orders that may be made applicable to related persons include those that deny or affect export privileges, including temporary denial orders * * * .'' 15 CFR 766.23(a). *See also* 15 CFR 766.24(c) (''A temporary denial order may be made applicable to related persons in accordance with § 766.23 of this part.'').

B. Analysis and Findings

Via a notice letter sent in accordance with Section 766.23 of the Regulations on December 31, 2012, OEE provided Mr. Bahrami with notice of its intent to seek an order adding him to the TDO as a related person to Mahan Airways, in

[8] The Airbus A310 is powered with U.S.-origin engines. The engines are subject to the EAR and classified under Export Control Classification (''ECCN'') 9A991.d. The Airbus A310 contains controlled U.S.-origin items valued at more than 10 percent of the total value of the aircraft and as a result is subject to the EAR. The aircraft is classified under ECCN 9A991.b. The reexport of this aircraft to Iran requires U.S. Government authorization pursuant to Section 746.7 of the Regulations.

[9] The renewal request that led to the renewal of this TDO on August 9, 2012, was submitted before OEE detected this shipment and issued the redelivery order.

[10] Mahan Airways was designated by OFAC as a SDGT on October 18, 2011. 77 Fed. Reg. 64,427 (October 18, 2011).

order to prevent evasion. No response has been received from Bahrami.

OEE has presented evidence that Bahrami is a Mahan Airways' Vice-President and Regional Manager for Turkey and Europe, and is based in Mahan Airways' Istanbul office. As discussed *supra,* Mahan Airways has made repeated recent attempts to evade the TDO by procuring, via Turkey, U.S.-origin aircraft engines and other aircraft parts in violation of the TDO and the Regulations. In addition, as summarized *supra,* Mahan Airways previously procured an A310 subject to the Regulations from Germany, via the Ukraine.

OEE also has presented evidence showing that Bahrami was at least aware of Ali Eslamian's attempt to procure a U.S.-origin aircraft engine from Brazil, via Turkey, for Mahan Airways, as described in detail in the August 9, 2012 Renewal Order.[11] OEE also has obtained and submitted a copy of a witness statement signed and dated by Bahrami as of May 31, 2009, that was entered into evidence by Mahan Airways in the U.K. litigation between Mahan and the Balli Group regarding Aircraft 1–3. In that witness statement, Bahrami testified, *inter alia,* that he had joined Mahan in Airways in 1997 and that, in addition to his positions directly with Mahan Airways, he was the director and sole shareholder of Blue Sky Aviation FZE, which he stated ''[was] and always [had] been, for all purposes owned and controlled by Mahan Air.'' Bahrami Witness Statement, at ¶¶ 1–2, 4. He further testified that Blue Sky Aviation FZE's ''role in the acquisition of three Boeing 747[s] is clear and obvious from all the documents signed on its behalf[,]'' that it had ''acted at all times on the instructions of senior management at Mahan and got full legal tile to the three Boeing 747 aircraft in October 2008[,]'' and thereafter had ''dry leased the aircraft to Mahan Air[.]'' *Id.,* at ¶¶ 5–6.

Given Bahrami's management position with regard to Mahan Airways' operations in Turkey and Europe and Mahan's continuing efforts to procure U.S.-origin aircraft and engines from or via Turkey and Europe, as well as Bahrami's prior role in the acquisition and leasing to Mahan of the three Boeing 747s (Aircraft 1–3) that originated this TDO, and his demonstrated, long-standing willingness to act in concert with and at the direction of Mahan's senior management in Tehran, it is clear that he is a related person to Mahan and that a significant risk of evasion and further violations exist absent his addition to the TDO.

In sum, I find pursuant to Section 766.23 that Mehdi Bahrami is a related person to Mahan Airways and that his addition to the TDO is necessary to prevent evasion of the TDO.

IV. Order

It is therefore ordered:

First, that MAHAN AIRWAYS, Mahan Tower, No. 21, Azadegan St., M.A. Jenah Exp. Way, Tehran, Iran; ZARAND AVIATION A/K/A GIE ZARAND AVIATION, 42 Avenue Montaigne, 75008 Paris, France, and 112 Avenue Kleber, 75116 Paris, France; GATEWICK LLC, A/K/A GATEWICK FREIGHT & CARGO SERVICES, A/K/A GATEWICK AVIATION SERVICE, G#22 Dubai Airport Free Zone, P.O. Box 393754, Dubai, United Arab Emirates, and P.O. Box 52404, Dubai, United Arab Emirates, and Mohamed Abdulla Alqaz Building, Al Maktoum Street, Al Rigga, Dubai, United Arab Emirates; PEJMAN MAHMOOD KOSARAYANIFARD A/K/A KOSARIAN FARD, P.O. Box 52404, Dubai, United Arab Emirates; MAHMOUD AMINI, G#22 Dubai Airport Free Zone, P.O. Box 393754, Dubai, United Arab Emirates, and P.O. Box 52404, Dubai, United Arab Emirates, and Mohamed Abdulla Alqaz Building, Al Maktoum Street, Al Rigga, Dubai, United Arab Emirates; KERMAN AVIATION A/K/A GIE KERMAN AVIATION, 42 Avenue Montaigne 75008, Paris, France; SIRJANCO TRADING LLC, P.O. Box 8709, Dubai, United Arab Emirates; ALI ESLAMIAN, 4th Floor, 33 Cavendish Square, London W1G0PW, United Kingdom, and 2 Bentinck Close, Prince Albert Road St. Johns Wood, London NW87RY, United Kingdom; MAHAN AIR GENERAL TRADING LLC, 19th Floor Al Moosa Tower One, Sheik Zayed Road, Dubai 40594, United Arab Emirates; SKYCO (UK) LTD., 4th Floor, 33 Cavendish Square, London, W1G 0PV, United Kingdom; EQUIPCO (UK) LTD., 2 Bentinck Close, Prince Albert Road, London, NW8 7RY, United Kingdom; and MEDHI BAHRAMI,, Mahan Airways- Istanbul Office, Cumhuriye Cad. Sibil Apt No: 101 D:6, 34374 Emadad, Sisli Istanbul, Turkey, and when acting for or on their behalf, any successors or assigns, agents, or employees (each a ''Denied Person'' and collectively the ''Denied Persons'') may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the Export Administration Regulations (''EAR''), or in any other activity subject to the EAR including, but not limited to:

A. Applying for, obtaining, or using any license, License Exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the EAR, or in any other activity subject to the EAR; or

C. Benefiting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the EAR, or in any other activity subject to the EAR.

Second, that no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of a Denied Person any item subject to the EAR;

B. Take any action that facilitates the acquisition or attempted acquisition by a Denied Person of the ownership, possession, or control of any item subject to the EAR that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby a Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from a Denied Person of any item subject to the EAR that has been exported from the United States;

D. Obtain from a Denied Person in the United States any item subject to the EAR with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the EAR that has been or will be exported from the United States and which is owned, possessed or controlled by a Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by a Denied Person if such service involves the use of any item subject to the EAR that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing. THIRD, that, after notice and opportunity for comment as provided in section 766.23 of the EAR, any other person, firm, corporation, or business organization related to a Denied Person by affiliation,

[11] Among other things, Eslamian signed a letter of intent with a Brazilian airline on November 20, 2009, and subsequently signed a sales and purchase agreement for the engine in April 2010. Eslamian's efforts to acquire the engine for Mahan Airways continued at least as recently as December 2011.

ownership, control, or position of responsibility in the conduct of trade or related services may also be made subject to the provisions of this Order. FOURTH, that this Order does not prohibit any export, reexport, or other transaction subject to the EAR where the only items involved that are subject to the EAR are the foreign-produced direct product of U.S.-origin technology.

In accordance with the provisions of Sections 766.24(e) of the EAR, Mahan Airways and/or Zarand Aviation may, at any time, appeal this Order by filing a full written statement in support of the appeal with the Office of the Administrative Law Judge, U.S. Coast Guard ALJ Docketing Center, 40 South Gay Street, Baltimore, Maryland 21202–4022. In accordance with the provisions of Sections 766.23(c)(2) and 766.24(e)(3) of the EAR, Gatewick LLC, Mahmoud Amini, Kosarian Fard, Kerman Aviation, Sirjanco Trading LLC, Ali Eslamian, Mahan Air General Trading LLC, Skyco (UK) Ltd., Equipco (UK) Ltd., and/or Medhi Bahrami may, at any time, appeal their inclusion as a related person by filing a full written statement in support of the appeal with the Office of the Administrative Law Judge, U.S. Coast Guard ALJ Docketing Center, 40 South Gay Street, Baltimore, Maryland 21202–4022.

In accordance with the provisions of Section 766.24(d) of the EAR, BIS may seek renewal of this Order by filing a written request not later than 20 days before the expiration date. A renewal request may be opposed by Mahan Airways and/or Zarand Aviation as provided in Section 766.24(d), by filing a written submission with the Assistant Secretary of Commerce for Export Enforcement, which must be received not later than seven days before the expiration date of the Order.

A copy of this Order shall be provided to Mahan Airways, Zarand Aviation and each related person and shall be published in the **Federal Register**. This Order is effective immediately and shall remain in effect for 180 days.

Dated: February 4, 2013.

David W. Mills,

Assistant Secretary of Commerce for Export Enforcement.

[FR Doc. 2013–02867 Filed 2–7–13; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–924]

Polyethylene Terephthalate Film, Sheet, and Strip From the People's Republic of China: Notice of Court Decision Not in Harmony With Final Results of Administrative Review and Notice of Amended Final Results of Administrative Review Pursuant to Court Decision

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On January 24, 2013 the United States Court of International Trade (''CIT'') sustained the Department of Commerce's (''the Department'') results of redetermination, pursuant to the CIT's remand order, in *Fuwei Films (Shandong) Co., Ltd.* v. *United States,* Slip Op. 13–10 (CIT 2013).[1]

Consistent with the decision of the United States Court of Appeals for the Federal Circuit (''CAFC'') in *Timken Co.* v. *United States,* 893 F.2d 337 (Fed. Cir. 1990) (''*Timken*''), as clarified by *Diamond Sawblades Mfrs. Coalition* v. *United States,* 626 F.3d 1374 (Fed. Cir. 2010) (''*Diamond Sawblades*''), the Department is notifying the public that the final judgment in this case is not in harmony with the Department's *PET Film Final Results* [2] and is amending the final results with respect to Fuwei Films (Shandong) Co., Ltd. and Shaoxing Xiangyu Green Packing Co., Ltd.

DATES: *Effective Date:* (February 4, 2013) [3].

FOR FURTHER INFORMATION CONTACT: Jonathan Hill, Office 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW, Washington, DC, 20230; telephone: (202) 482–3518.

SUPPLEMENTARY INFORMATION:

Background

On June 1, 2012, the CIT remanded three issues with respect to the *PET Film Final Results,* two of which the Department requested for voluntary remand.[4] Specifically, the CIT held that: (1) The Department must correct Shaoxing Xiangyu Green Packing Co. Ltd.'s (''Green Packing'') per unit water and electricity costs; (2) the Department must reconsider the surrogate value (''SV'') for labor expenses; and (3) the Department must clarify or reconsider the SV for polyethylene terephthalate (''PET'') chips.

Pursuant to the CIT's remand instructions, the Department re-examined record evidence and made the following changes. First, the Department revised its calculation of Green Packing's reported per-unit water and electricity consumption. To correct the error, the Department has assigned Green Packing's reported electricity factor to the calculated water input, and Green Packing's reported water factor to the calculated electricity input, in the calculation of Green Packing's cost of production.

Next, the Department revised its calculation for the labor SV in accordance with *Labor Methodologies* by using the reported 2008 ILO Chapter 6A data provided under the International Standard Industrial Classification Revision.3–D standard, the most contemporaneous Chapter 6A data that were available at the time the Department conducted the underlying review.[5]

Finally, the Department revised its calculation of the PET chip input SV by using import data exclusively from Indian harmonized tariff schedule category 3907.60.10.

Timken Notice

In its decision in *Timken,* 893 F.2d at 341, as clarified by *Diamond Sawblades,* the CAFC has held that, pursuant to section 516A(e) of the Tariff Act of 1930, as amended (the ''Act''), the Department must publish a notice of a court decision that is not ''in harmony'' with a Department determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The CIT's January 24, 2013, judgment sustaining the *PET Film Final Remand* constitutes a final decision of that court that is not in harmony with the *PET Film Final Results.* This notice is published in fulfillment of the

[1] *See* Final Results of Redetermination Pursuant to Court Remand, Court No. 11–00061, dated October 15, 2012, available at: *http://ia.ita.doc.gov/remands* (*''PET Film Final Remand''*); *see also Fuwei Films (Shandong) Co., Ltd.* v. *United States,* Consol. Court No. 11–00061, Slip Op. 12–69 (CIT 2012) (*''Remand Opinion and Order''*).

[2] *See Polyethylene Terephthalate Film, Sheet, and Strip From the People's Republic of China: Final Results of the First Antidumping Duty Administrative Review,* 76 FR 9753 (February 22, 2011) (*''PET Film Final Results''*).

[3] Because the deadline, February 3, 2013, falls on a Sunday, the deadline is postponed until the next business day. *See Notice of Clarification: Application of ''Next Business Day'' Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, as Amended,* 70 FR 24533 (May 10, 2005).

[4] *See Remand Opinion and Order.*

[5] *See Antidumping Methodologies in Proceedings Involving Non-Market Economies: Valuing the Factor of Production: Labor,* 76 FR 36092 (June 21, 2011) (*''Labor Methodologies''*).

publication requirements of *Timken.* Accordingly, the Department will continue the suspension of liquidation of the subject merchandise pending the expiration of the period of appeal or, if appealed, pending a final and conclusive court decision. The cash deposit rate will remain the company-specific rate established for the subsequent and most recent period during which each respondent was reviewed.

Amended Final Determination

Because there is now a final court decision with respect to the *PET Film Final Results,* the revised dumping margins are as follows:

Exporter	Weighted-average margin (percent)
Fuwei Films (Shandong) Co., Ltd	0.27
Shaoxing Xiangyu Green Packing Co., Ltd	0.00

This notice is issued and published in accordance with sections 516A(e)(1), 751(a)(1), and 777(i)(1) of the Act.

Dated: February 4, 2013.

Paul Piquado,

Assistant Secretary for Import Administration.

[FR Doc. 2013–02911 Filed 2–7–13; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–475–818]

Certain Pasta From Italy: Notice of Final Results of 15th Antidumping Duty Administrative Review, Final No Shipment Determination and Revocation of Order, in Part; 2010–2011

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on certain pasta from Italy. The period of review (POR) is July 1, 2010, through June 30, 2011. The review covers two mandatory respondents, Pastificio Attilio Mastromauro Granoro S.r.L. (Granoro), and Rummo S.p.A. Molino e Pastificio and its affiliates (Rummo), and five non-selected companies.[1] Based on our analysis of the comments received, we have made certain changes in the margin calculations from the preliminary results for Rummo and its affiliates. We have made no changes with respect to Granoro. The final weighted-average dumping margins for the reviewed firms are listed below in the section entitled ''Final Results of Review.''

DATES: *Effective Date:* February 8, 2013.

FOR FURTHER INFORMATION CONTACT: Stephanie Moore (Granoro) or George McMahon (Rummo), AD/CVD Operations, Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–3692 or (202) 482–1167, respectively.

SUPPLEMENTARY INFORMATION:

Background

On August 3, 2012, the Department published the preliminary results of the 2010–2011 administrative review of the antidumping duty order on certain pasta from Italy.[2] On October 26, 2012, Rummo and Granoro submitted a case brief. On November 5, 2012, the petitioners submitted a rebuttal brief with respect to Rummo. On December 26, 2012, the Department issued a targeted dumping post-preliminary analysis and invited interested parties to comment.[3] On January 7, 2013, Rummo filed comments regarding the Department's post-preliminary analysis. On January 10, 2013, the petitioners field a rebuttal comments to Rummo's post-preliminary comments. We received no comments regarding the post-preliminary analysis with respect to Granoro.

Scope of the Order [4]

Imports covered by the order are shipments of certain non-egg dry pasta. The merchandise subject to review is currently classifiable under items 1901.90.90.95 and 1902.19.20 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to the order is dispositive.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to this administrative review are addressed in the ''Issues and Decision Memorandum for the Final Results of the 15th Administrative Review of the Antidumping Duty Order on Certain Pasta from Italy; 2010–2011,'' from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations to Paul Piquado, Assistant Secretary for Import Administration, (Issues and Decision Memorandum), dated concurrently with this notice and which is hereby adopted by this notice. A list of the issues which parties have raised, and to which we have responded in the Issues and Decision Memorandum, is attached to this notice as an Appendix. The Issues and Decision Memorandum is a public document and is on file electronically via Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System (IA ACCESS). IA ACCESS is available in the Central Records Unit, main Commerce Building, Room 7046. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Web at *http://ia.ita.doc.gov/frn/.* The signed Issues and Decision Memorandum and electronic version of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Based on our analysis of comments received for Rummo, we have recalculated Rummo's weighted-average dumping margin. Rummo's adjustments are discussed in detail in the accompanying final calculation memorandum.[5] As a result of the aforementioned recalculation of Rummo's rate and as we have excluded

[1] The non-selected companies are: Botticelli Mediterraneo S.a.r.l. (Botticelli), Fiamma Vesuviana S.r.L. (Fiamma), Industria Alimentare Filiberto Bianconi 1947 S.p.A. (Filiberto), Pastificio Fratelli Cellino, S.r.l. (Cellino), and Pastificio Zaffiri (Zaffiri).

[2] *See Certain Pasta from Italy: Notice of Preliminary Results of Antidumping Duty Administrative Review,* 77 FR 46377 (August 3, 2012) (*Preliminary Results*).

[3] *See* Memorandum to Lynn Fischer Fox, Deputy Assistant Secretary for Policy and Negotiations from Gary Taverman, Senior Advisor for Antidumping and Countervailing Duty Operations, titled 2010/2011 Review of the Antidumping Duty Order on Certain Pasta from Italy: Post-Preliminary Analysis (Post-Preliminary Analysis) dated December 26, 2012.

[4] For a complete description, including the exclusions to the scope, see *Preliminary Results.* On October 10, 2012, the Department revised the ''Scope of the Order'' to recognize the EU-authorized Italian agents for purposes of the antidumping and countervailing duty orders on pasta from Italy. *See* Memorandum from Yasmin Nair to Susan Kuhbach, titled ''Recognition of EU Organic Certifying Agents for Certifying Organic Pasta from Italy,'' dated October 10, 2012, which is on file in the Department's CRU. We have adopted this scope decision in this current administrative review of certain pasta from Italy.

[5] *See* Memorandum to the File titled ''Calculation Memorandum for Rummo S.p.A. Molino e Pastificio and its affiliates (Rummo) for the Final Results of the 15th Administrative Review of Certain Pasta from Italy,'' dated February 1, 2013.

the *de minimis* rate calculated for Granoro, the weighted-average dumping margin for the three non-selected companies has changed. The *de minimis* rate calculated for Granoro remains unchanged from the *Preliminary Results.*

Petitioners' Targeted Dumping Allegation

As noted in the *Preliminary Results,* the petitioners asserted that the Department should use an alternative comparison method for Granoro and Rummo based on their allegations of targeted dumping.[6] The petitioners argue the Department should conduct a targeted dumping analysis, as currently applied in antidumping investigations, and employ average-to-transaction comparisons without offsets should the Department find that the record supports its allegation of targeted dumping.[7] The Department issued a post-preliminary analysis to address petitioners' targeted dumping allegation on December 26, 2012.[8]

As a result of the application of its targeted dumping analysis, the Department continues to find for Granoro that a pattern of export prices (or constructed export prices) for comparable merchandise that differ significantly among certain purchasers, regions, and time periods exists.[9] For Granoro, because this methodology does not yield a weighted-average dumping margin that is meaningfully different than the weighted-average dumping calculated using the average-to-transaction (A-to-T) methodology, the Department finds that the observed price differences can be taken into account by the average-to-average (A-to-A) method. For Rummo, there does not exist a pattern of export prices (or constructed export prices) for comparable merchandise that differs significantly among consumers, regions, or time periods, and, thus, we have used the A-to-A method to calculate Rummo's weighted-average dumping margin on certain pasta from Italy for the POR.

Determination of No Reviewable Entries

On August 30, 2011, and September 6, 2011, Fiamma [10] and Botticelli,[11] respectively, reported to the Department that neither company had any exports, sales or entries of subject merchandise to the United States during the POR. In the *Preliminary Results,* the Department issued its ''Preliminary Determination of No Reviewable Entries'' with respect to Fiamma and Botticelli and stated ''{b}ecause ''as entered'' liquidation instructions do not alleviate the concerns which the *Assessment Policy Notice* [12] was intended to address, instead of rescinding the review with respect to Botticelli and Fiamma, we find it appropriate to complete the review and issue liquidation instructions to U.S. Customs and Border Protection (CBP) concerning entries for these companies following the final results of the review.'' [13]

We received no comments from interested parties regarding these companies and continue to find no reviewable entries. Accordingly, pursuant to the *Assessment Policy Notice* (''automatic assessment'' clarification), we intend to instruct CBP to liquidate any existing entries of merchandise produced by Botticelli and Fiamma but exported by other parties at the all-others rate.[14]

Final Results of Review

We determine that the following weighted-average dumping margins exist for the period July 1, 2010, through June 30, 2011:

Manufacturer/ exporter	Weighted-average dumping margin (percent) [15]
Rummo	5.11
Granoro	0.00
Review-Specific Average Rate [16] Applicable to the Following Companies: Filiberto, Cellino, and Zaffiri	5.11

Duty Assessment

The Department shall determine and CBP shall assess antidumping duties on all appropriate entries. For any individually examined respondents whose weighted-average dumping margin is above *de minimis,* we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1).[17] Upon issuance of the final results of this administrative review, if any importer-specific assessment rates calculated in the final results are above *de minimis* (*i.e.,* at or above 0.5 percent), the Department will issue appraisement instructions directly to CBP to assess antidumping duties on appropriate entries.

To determine whether the duty assessment rates covering the period were *de minimis,* in accordance with the requirement set forth in 19 CFR 351.106(c)(2), for each respondent we calculated importer (or customer)-specific *ad valorem* rates by aggregating the amount of dumping calculated for all U.S. sales to that importer or customer and dividing this amount by the total entered value of the sales to that importer (or customer). Where an importer (or customer)-specific *ad valorem* rate is greater than *de minimis,* and the respondent has reported reliable entered values, we apply the assessment rate to the entered value of the importer's/customer's entries during the review period. Where an importer (or

[6] *See* the petitioners' allegation of targeted dumping with respect to Granoro, dated April 20, 2012, at 1–8, and the petitioners' allegation of targeted dumping with respect to Rummo, dated April 20, 2012, at 1–8, both (citing *Certain Steel Nails from the People's Republic of China: Final Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances,* 73 FR 33,977 (June 16, 2008) (*Steel Nails*), and accompanying Issues and Decision Memorandum at Comment 8; *Multilayered Wood Flooring from the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 76 FR 64318 (October 18, 2011) (*Wood Flooring*), and accompanying Issues and Decision Memorandum (IDM) at Comment 4.

[7] *See* the Department's accompanying IDM at Comment 6.

[8] *See* Post-Preliminary Analysis.

[9] *See* the IDM at Comment 6.

[10] In its letter of August 30, 2011, Fiamma stated that ''Fiamma Vesuviana hereby informs the Department of Commerce that it had no exports, sales or entries of pasta subject to the antidumping order on pasta from Italy to the United States during the period of review, July 1, 2010 through June 30, 2011.''

[11] In its letter of September 6, 2011, Botticelli stated, ''Botticelli Mediterraneo further informs the Department of Commerce that it is located in Tunisia; that it produces and exports olive oil and is not involved in the production, distribution or sale of pasta in any way; and that it does not have any operations of any type in Italy.''

[12] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003) (*Automatic Assessment Clarification*).

[13] *See Preliminary Results* at 46379.

[14] *See, e.g., Magnesium Metal From the Russian Federation: Preliminary Results of Antidumping Duty Administrative Review,* 75 FR 26922, 26923 (May 13, 2010), unchanged in *Magnesium Metal From the Russian Federation: Final Results of Antidumping Duty Administrative Review,* 75 FR 56989 (September 17, 2010).

[15] The weighted-average dumping margins for Granoro and Rummo include an adjustment for the countervailing duty offset to account for the export subsidy portion of the countervailing duties applied to these companies, as defined in the field CVDU.

[16] This rate is based on the rates for the respondents that were selected for individual review, excluding rates that are zero, *de minimis* or based entirely on facts available.

[17] In these final results, the Department applied the assessment rate calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012).

customer)-specific *ad valorem* rate is greater than *de minimis* and we do not have reliable entered values, we calculate a per-unit assessment rate by aggregating the amount of dumping for all U.S. sales to each importer (or customer) and dividing this amount by the total quantity sold to that importer (or customer).

The Department clarified its ''automatic assessment'' regulation on May 6, 2003.[18] This clarification will apply to entries of subject merchandise during the POR produced by the respondent for which it did not know its merchandise was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction. For a full discussion of this clarification, see the *Automatic Assessment Clarification.*

Cash Deposit Requirements

The following cash deposit rates will be effective upon publication of the final results of this administrative review for all shipments of pasta from Italy entered, or withdrawn from warehouse, for consumption on or after the publication date of these final results, as provided for by section 751(a)(1) of the Tariff Act of 1930, as amended (the Act): (1) The cash deposit rate for companies subject to this review will be the rate established in the final results of this review, except if the rate is less than 0.5 percent and, therefore, *de minimis,* no cash deposit will be required; (2) if the exporter is not a firm covered in this review, but was covered in a previous review or the original less-than-fair-value (LTFV) investigation, the cash deposit rate will continue to be the company-specific rate established for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the LTFV investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the subject merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered by this review, a prior review, or the LTFV investigation, the cash deposit rate will be 15.45 percent, the all-others rate established in the Section 129 determination.[19] These cash deposit requirements shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent increase in antidumping duties by the amount of antidumping and/or countervailing duties reimbursed.

Notification Regarding APOs

This notice also serves as a reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(5). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

This administrative review and notice are in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: February 1, 2013.

Paul Piquado,

Assistant Secretary for Import Administration.

Appendix I

List of Comments in the Issues and Decision Memorandum

Comment 1: Whether the Department Should Collapse the Reported Control Numbers for Granoro

Comment 2: Whether the Department Should Offset Transport Recovery Against U.S. Freight for Granoro

Comment 3: Whether the Department Erred in Applying Quarterly Cost to Granoro

Comment 4: Whether the Department Should Continue To Rely on Protein Content Based on the Nutritional Label

Comment 5: Whether the Department Should Review All of Rummo's EP Entries During the POR

Comment 6: Analysis of Targeted Dumping Allegation

[FR Doc. 2013–02909 Filed 2–7–13; 8:45 am]

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[18] *See Automatic Assessment Clarification.*

[19] *See Implementation of the Findings of the WTO Panel in US—Zeroing (EC): Notice of Determinations Under Section 129 of the Uruguay Round Agreements Act and Revocations and Partial Revocations of Certain Antidumping Duty Orders,* 72 FR 25261 (May 4, 2007).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–820]

Fresh Tomatoes From Mexico: Intent To Terminate Suspension Agreement and Resume Antidumping Investigation and Intent To Terminate Sunset Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On February 2, 2013, the Department of Commerce (the Department) and Mexican tomato growers/exporters accounting for a significant percentage of all fresh tomatoes imported into the United States from Mexico initialed a draft agreement that would suspend a resumed antidumping investigation on fresh tomatoes from Mexico. Based on this draft agreement, and if an acceptable agreement is reached, we anticipate that the Mexican tomato growers/exporters will withdraw from the 2008 Agreement in order to enter into a new agreement. If the Mexican tomato growers/exporters withdraw from the 2008 Agreement, the Agreement will no longer cover substantially all imports of fresh tomatoes from Mexico. Accordingly, the Department of Commerce would terminate the suspension agreement and resume the antidumping investigation. In addition, in the event the Department terminates the suspension agreement and resumes the investigation, the Department intends to terminate the ongoing sunset review. Conclusion of a new agreement would result in suspension of the resumed investigation.

DATES: *Effective Date:* February 8, 2013.

FOR FURTHER INFORMATION CONTACT: Judith Wey Rudman or Julie Santoboni at (202) 482–0192 or (202) 482–3063, respectively; Office of Policy, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street & Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On April 18, 1996, the Department initiated an antidumping investigation to determine whether imports of fresh tomatoes from Mexico are being, or are likely to be, sold in the United States at less than fair value (LTFV) (61 FR 18377, April 25, 1996). On May 16, 1996, the United States International Trade Commission (ITC) notified the

Department of its affirmative preliminary injury determination.

On October 10, 1996, the Department and Mexican tomato growers/exporters initialed a proposed agreement to suspend the antidumping investigation. On October 28, 1996, the Department preliminarily determined that imports of fresh tomatoes from Mexico are being sold at LTFV in the United States. *See Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Fresh Tomatoes from Mexico,* 61 FR 56608 (November 1, 1996) (*Preliminary Determination*). On the same day on which the Department issued the *Preliminary Determination,* the Department and certain growers/exporters of fresh tomatoes from Mexico signed an agreement to suspend the investigation (1996 Suspension Agreement). *See Suspension of Antidumping Investigation: Fresh Tomatoes from Mexico,* 61 FR 56618 (November 1, 1996).

On May 31, 2002, Mexican tomato growers/exporters accounting for a significant percentage of all fresh tomatoes imported into the United States from Mexico provided written notice to the Department of their withdrawal from the 1996 Suspension Agreement, effective July 30, 2002. Because the 1996 Suspension Agreement would no longer cover substantially all imports of fresh tomatoes from Mexico, effective July 30, 2002, the Department terminated the 1996 Suspension Agreement, terminated the sunset review of the suspended investigation, and resumed the antidumping investigation. *See Notice of Termination of Suspension Agreement, Termination of Sunset Review, and Resumption of Antidumping Investigation: Fresh Tomatoes from Mexico,* 67 FR 50858 (August 6, 2002).

On November 8, 2002, the Department and Mexican tomato growers/exporters initialed a proposed agreement suspending the resumed antidumping investigation on imports of fresh tomatoes from Mexico. On December 4, 2002, the Department and certain growers/exporters of fresh tomatoes from Mexico signed a new suspension agreement (2002 Suspension Agreement). *See Suspension of Antidumping Investigation: Fresh Tomatoes From Mexico,* 67 FR 77044 (December 16, 2002). On November 3, 2003, the Department published the *Final Results of Analysis of Reference Prices and Clarifications and Corrections; Agreement Suspending the Antidumping Duty Investigation on Fresh Tomatoes From Mexico,* 68 FR 62281 (November 3, 2003).

On November 26, 2007, Mexican tomato growers/exporters accounting for a significant percentage of all fresh tomatoes imported into the United States from Mexico provided written notice to the Department of their withdrawal from the 2002 Suspension Agreement, effective 90 days from the date of their withdrawal letter (*i.e.,* February 24, 2008), or earlier, at the Department's discretion.

On November 28, 2007, the Department and Mexican tomato growers/exporters initialed a new proposed agreement to suspend the antidumping investigation on imports of fresh tomatoes from Mexico. On December 3, 2007, the Department released the initialed agreement to interested parties and afforded them an opportunity to comment on the initialed agreement. On December 17 and 18, 2007, several interested parties filed comments in support of the initialed agreement.

Because the 2002 Suspension Agreement would no longer cover substantially all imports of fresh tomatoes from Mexico, the Department published a notice of intent to terminate the 2002 Suspension Agreement, intent to terminate the five-year sunset review of the suspended investigation, and intent to resume the antidumping investigation. *See Fresh Tomatoes from Mexico: Notice of Intent to Terminate Suspension Agreement, Intent to Terminate the Five-Year Sunset Review, and Intent to Resume Antidumping Investigation,* 72 FR 70820 (December 13, 2007). On January 16, 2008, the Department published a notice of termination of the 2002 Suspension Agreement, termination the five-year sunset review of the suspended investigation, and resumption of the antidumping investigation, effective January 18, 2008. *See Fresh Tomatoes from Mexico: Notice of Termination of Suspension Agreement, Termination of Five-Year Sunset Review, and Resumption of Antidumping Investigation,* 73 FR 2887 (January 16, 2008).

On January 22, 2008, the Department signed a new suspension agreement (2008 Suspension Agreement) with certain growers/exporters of fresh tomatoes from Mexico. *See Suspension of Antidumping Investigation: Fresh Tomatoes from Mexico,* 73 FR 4831 (January 28, 2008).

On August 15, 2012, certain Mexican growers/exporters filed a letter with the Department requesting consultations under section IV.G. of the 2008 Suspension Agreement and the Department agreed to consult. As a result of these consultations, on February 2, 2013, the Department and Mexican tomato growers/exporters accounting for a significant percentage of all fresh tomatoes imported into the United States from Mexico initialed a draft agreement that would suspend a resumed antidumping investigation on fresh tomatoes from Mexico.

Scope of the Investigation

The merchandise subject to the suspended investigation is all fresh or chilled tomatoes (fresh tomatoes) which have Mexico as their origin, except for those tomatoes which are for processing. For purposes of this suspended investigation, processing is defined to include preserving by any commercial process, such as canning, dehydrating, drying, or the addition of chemical substances, or converting the tomato product into juices, sauces, or purees. Fresh tomatoes that are imported for cutting up, not further processing (*e.g.,* tomatoes used in the preparation of fresh salsa or salad bars), are covered by this Agreement.

Commercially grown tomatoes, both for the fresh market and for processing, are classified as Lycopersicon esculentum. Important commercial varieties of fresh tomatoes include common round, cherry, grape, plum, greenhouse, and pear tomatoes, all of which are covered by this investigation.

Tomatoes imported from Mexico covered by this suspended investigation are classified under the following subheadings of the Harmonized Tariff Schedules of the United States (HTSUS), according to the season of importation: 0702 and 9906.07.01 through 9906.07.09. Although the HTSUS numbers are provided for convenience and customs purposes, the written description of the scope of this suspended investigation is dispositive.

Intent To Terminate Suspension Agreement and Resume the Antidumping Investigation

Based on the initialed draft agreement, and if an acceptable agreement is reached, we anticipate that the Mexican tomato growers will withdraw from the 2008 Suspension Agreement. If the growers/exporters accounting for a significant percentage of exports of tomatoes to the United States withdraw from the 2008 Suspension Agreement, the 2008 Suspension Agreement will no longer cover substantially all imports of fresh tomatoes from Mexico. Accordingly, the Department would terminate the 2008 Suspension Agreement and resume the antidumping investigation in

accordance with section 734(i)(1)(B) of the Tariff Act of 1930, as amended (the Act). Pursuant to section 734(i)(1)(B) of the Act, the Department would resume the investigation as if it had published the affirmative preliminary determination under section 733(b) of the Act on the effective date of the termination. As explained in the *Preliminary Determination* (61 FR at 56609), the Department postponed the final determination until the 135th day after the date of the preliminary determination. The Department therefore would make its final determination in a resumed investigation within 135 days of termination of the 2008 Suspension Agreement, unless a new suspension agreement becomes effective. However, if the Department and substantially all of the growers/exporters of fresh tomatoes from Mexico sign a new suspension agreement, following the notice and comment period provided in accordance with section 734(c) of the Act, the resumed investigation would be suspended.

Intent To Terminate the Five-Year Sunset Review

On December 3, 2012, the Department initiated a five-year sunset review of the suspended antidumping investigation on fresh tomatoes from Mexico pursuant to section 751(c) of the Act. *See Initiation of Five-Year (''Sunset'') Review,* 77 FR 71684 (December 3, 2012).

If the Department terminates the 2008 Suspension Agreement, there will no longer be a suspended investigation of which to conduct a sunset review. Therefore, the Department would terminate the sunset review of the suspended antidumping investigation on fresh tomatoes from Mexico, effective on the date of termination of the 2008 Suspension Agreement.

International Trade Commission

The Department has notified the International Trade Commission (ITC) of its intent to terminate the 2008 Suspension Agreement and resume the antidumping investigation. If the Department resumes the antidumping investigation, and if the Department makes a final affirmative determination in the investigation, the ITC is scheduled to make its final determination concerning injury within 45 days of publication of the Department's final determination. If both the Department's and the ITC's final determinations are affirmative, the Department will issue an antidumping duty order. However, as indicated above, if the Department and substantially all of the growers/exporters of fresh tomatoes from Mexico sign a new suspension agreement, following the notice and comment period provided in accordance with section 734(c) of the Act, the resumed investigation would be suspended.

Suspension of Liquidation

If the Department terminates the 2008 Suspension Agreement and resumes the antidumping investigation as described above, the Department will instruct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of fresh tomatoes from Mexico that are entered, or withdrawn from warehouse, for consumption on or after the effective date of the termination of the 2008 Suspension Agreement. CBP shall require antidumping duty cash deposits or bonds for entries of the subject merchandise based on the preliminary dumping margins, which range from 4.16 to 188.45 percent. *See Preliminary Determination,* 61 FR at 56615.

Administrative Protective Order Access and Applicable Regulations

The following requirements will apply if and during such time as the investigation is resumed. Because of the significant changes made to the administrative protective order (APO) process since the investigation, the Department will issue a new APO for any resumed investigation that will supersede the previously issued firm-specific APOs. Those authorized applicants that were granted APOs during the original investigation, as indicated in the most recent APO service list on the Department's Web site, will continue to have access to business proprietary information under APO. Any new APO applications or necessary amendments for changes in staff under the pre-existing APOs should be submitted promptly, and in accordance with the Department's regulations currently in effect. *See* section 777(c)(1) of the Act; 19 CFR 351.103, 351.304, 351.305 and 351.306.

In addition, because of the significant changes made to the Department's filing and certification requirements since the investigation, including electronic filing, the Department intends to apply its current regulations and practices with regard to filing and certification, should the antidumping investigation be resumed. See 19 CFR 351.303(b) and (g). However, with respect to the procedures for the conduct of any resumed investigation generally, including any possible suspension thereof, the Department's regulations in effect in 1996 shall govern. *See* 19 CFR 351.701; *San Vicente Camalu SPR de Ri* v. *United States,* 491 F.Supp.2d 1186 (CIT 2007).

This determination is issued and published in accordance with section 733(f) and 734(i) of the Act.

Dated: February 4, 2013.

Paul Piquado,

Assistant Secretary for Import Administration.

[FR Doc. 2013–02914 Filed 2–7–13; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–944]

Certain Oil Country Tubular Goods From the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review; 2011

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (''the Department'') is conducting an administrative review of the countervailing duty order on certain oil country tubular goods (''OCTG'') from the People's Republic of China (''PRC''). The period of review (''POR'') is January 1, 2011, through December 31, 2011. We preliminarily determine that Wuxi Seamless Oil Pipe Co., Ltd. (''Wuxi'') and Jiangsu Chengde Steel Tube Share Co., Ltd. (''Jiangsu Chengde'') received countervailable subsidies during the POR.

DATES: *Effective Date:* February 8, 2013.

FOR FURTHER INFORMATION CONTACT: Joshua Morris or Christopher Siepmann, AD/CVD Operations, Office 1, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–1779 or (202) 482–7958, respectively.

Scope of the Order

The scope of the order consists of OCTG. The merchandise subject to the order is currently classified in the Harmonized Tariff Schedule of the United States (''HTSUS'') under item numbers: 7304.29.10.10, 7304.29.10.20, 7304.29.10.30, 7304.29.10.40, 7304.29.10.50, 7304.29.10.60, 7304.29.10.80, 7304.29.20.10, 7304.29.20.20, 7304.29.20.30, 7304.29.20.40, 7304.29.20.50, 7304.29.20.60, 7304.29.20.80, 7304.29.31.10, 7304.29.31.20, 7304.29.31.30, 7304.29.31.40, 7304.29.31.50, 7304.29.31.60, 7304.29.31.80, 7304.29.41.10,

7304.29.41.20, 7304.29.41.30, 7304.29.41.40, 7304.29.41.50, 7304.29.41.60, 7304.29.41.80, 7304.29.50.15, 7304.29.50.30, 7304.29.50.45, 7304.29.50.60, 7304.29.50.75, 7304.29.61.15, 7304.29.61.30, 7304.29.61.45, 7304.29.61.60, 7304.29.61.75, 7305.20.20.00, 7305.20.40.00, 7305.20.60.00, 7305.20.80.00, 7306.29.10.30, 7306.29.10.90, 7306.29.20.00, 7306.29.31.00, 7306.29.41.00, 7306.29.60.10, 7306.29.60.50, 7306.29.81.10, and 7306.29.81.50.

The OCTG coupling stock covered by the order may also enter under the following HTSUS item numbers: 7304.39.00.24, 7304.39.00.28, 7304.39.00.32, 7304.39.00.36, 7304.39.00.40, 7304.39.00.44, 7304.39.00.48, 7304.39.00.52, 7304.39.00.56, 7304.39.00.62, 7304.39.00.68, 7304.39.00.72, 7304.39.00.76, 7304.39.00.80, 7304.59.60.00,, 7304.59.80.15, 7304.59.80.20, 7304.59.80.25, 7304.59.80.30, 7304.59.80.35, 7304.59.80.40, 7304.59.80.45, 7304.59.80.50, 7304.59.80.55, 7304.59.80.60, 7304.59.80.65, 7304.59.80.70, and 7304.59.80.80. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description, available in *Certain Oil Country Tubular Goods From the People's Republic of China: Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order,* 75 FR 3203 (January 20, 2010), remains dispositive.

A full description of the scope of the order is contained in the memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations to Paul Piquado, Assistant Secretary for Import Administration, ''Decision Memorandum for Preliminary Results of Countervailing Duty Administrative Review: Certain Oil Country Tubular Goods from the People's Republic of China,'' dated concurrently with this notice (''Preliminary Decision Memorandum''), which is hereby adopted by this notice.

The Preliminary Decision Memorandum is a public document and is on file electronically *via* Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System (''IA ACCESS''). IA ACCESS is available to registered users at *http://iaaccess.trade.gov* and in the Central Records Unit, Room 7046 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly on the Internet at *http://www.trade.gov/ia/.* The signed Preliminary Decision Memorandum and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Methodology

The Department has conducted this review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (''the Act''). For each of the subsidy programs found countervailable, we preliminarily determine that there is a subsidy, *i.e.,* a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific. *See* sections 771(5)(B)and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and, section 771(5A) of the Act regarding specificity. *See* sections 776(a) and (b) of the Act.

In making these findings, we have relied, in part, on facts available and, because one or more respondents did not act to the best of their ability to respond to the Department's requests for information, we have drawn an adverse inference in selecting from among the facts otherwise available. *See* sections 776(a) and (b) of the Act. For further information, *see* ''Use of Facts Otherwise Available and Adverse Inferences'' in the Preliminary Decision Memorandum.

Finally, the Department was not able to make a preliminary determination of countervailability for certain programs because it requires additional information. *See* Preliminary Decision Memorandum at ''Analysis of Programs—II. Programs For Which More Information is Required.'' We intend to seek that information prior to our final results.

For a full description of the methodology underlying our conclusions, *see* Preliminary Decision Memorandum.

Preliminary Results of the Review

As a result of this review, we preliminarily determine a net subsidy rate of 7.33 percent for Wuxi and a net subsidy rate of 1.84 percent for Jiangsu Chengde for the period January 1, 2011, through December 31, 2011.

Disclosure and Public Comment

The Department will disclose to parties to this proceeding the calculations performed in reaching the preliminary results within five days of the date of publication of these preliminary results.[1] Due to the anticipated timing of the release of post-preliminary analysis memoranda, interested parties may submit written comments (case briefs) for this administrative review no later than one week after the issuance of the last post-preliminary analysis memorandum, and rebuttal comments (rebuttal briefs) within five days after the time limit for filing case briefs.[2] Pursuant to 19 CFR 351.309(d)(2), rebuttal briefs must be limited to issues raised in the case briefs. Parties who submit arguments are requested to submit with the argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce within 30 days after the date of publication of this notice.[3] Requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues to be discussed. If a request for a hearing is made, we will inform parties of the scheduled date for the hearing which will be held at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, at a time and location to be determined.[4] Parties should confirm by telephone the date, time, and location of the hearing.

Parties are reminded that briefs and hearing requests are to be filed electronically using IA ACCESS and that electronically filed documents must be received successfully in their entirety by 5 p.m. Eastern Time on the due date.

Unless the deadline is extended pursuant to section 751(a)(3)(A) of the Act, the Department will issue the final results of this administrative review, including the results of our analysis of the issues raised by the parties in their comments, within 120 days after issuance of these preliminary results.

Assessment Rates

Upon issuance of the final results, the Department shall determine, and U.S. Customs and Border Protection (''CBP'') shall assess, countervailing duties on all appropriate entries covered by this review. We intend to issue instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of the

[1] *See* 19 CFR 351.224(b).

[2] *See* 19 CFR 351.309(c)(1)(ii) and 351.309(d)(1).

[3] *See* 19 CFR 351.310(c).

[4] *See* 19 CFR 351.310.

notice of final results of administrative review for all shipments of OCTG from the PRC entered, or withdrawn from warehouse, for consumption on or after the date of publication as provided by section 751(a)(2) of the Act: (1) The cash deposit rate for Wuxi and Jiangsu Chengde will be the rate established in the final results of this administrative review; (2) for merchandise exported by manufacturers or exporters not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; (4) the cash deposit rate for all other manufacturers or exporters will continue to be 13.20 percent, the all-others rate established in *Certain Oil Country Tubular Goods from the People's Republic of China: Final Affirmative Countervailing Duty Determination, Final Negative Critical Circumstances Determination,* 74 FR 64045 (December 7, 2009). These cash deposit requirements, when imposed, shall remain in effect until further notice.

This administrative review and notice are in accordance with sections 751(a)(1) and 777(i) of the Act and 19 CFR 351.213.

Dated: February 1, 2013.

Paul Piquado,

Assistant Secretary for Import Administration.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

1. Scope of the Order
2. Use of Facts Otherwise Available and Adverse Inferences
3. Subsidies Valuation Information
4. Analysis of Programs

[FR Doc. 2013–02903 Filed 2–7–13; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Notice of Scope Rulings

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* February 8, 2013.

SUMMARY: The Department of Commerce (''Department'') hereby publishes a list of scope rulings and anticircumvention determinations made between July 1, 2012, and September 30, 2012. We intend to publish future lists after the close of the next calendar quarter.

FOR FURTHER INFORMATION CONTACT: Jamie Blair-Walker, AD/CVD Operations, China/NME Group, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: 202–482–2615.

SUPPLEMENTARY INFORMATION:

Background

The Department's regulations provide that the Secretary will publish in the **Federal Register** a list of scope rulings on a quarterly basis.[1] Our most recent notification of scope rulings was published on August 29, 2012.[2] This current notice covers all scope rulings and anticircumvention determinations made by Import Administration between July 1, 2012, and September 30, 2012, inclusive. As described below, subsequent lists will follow after the close of each calendar quarter.

Scope Rulings Made Between July 1, 2012, and September 30, 2012

People's Republic of China

A–570–504: Petroleum Wax Candles From the People's Republic of China

Requestor: FashionCraft-Excello, Inc.; six animal figurine candles are not within the scope of the antidumping duty order; August 14, 2012.

A–570–836: Glycine From the People's Republic of China

Requestor: GEO Specialty Chemicals, Inc. and Chattem Chemicals, Inc.; People's Republic of China-origin technical or crude glycine further processed in India is within the scope of the antidumping duty order; preliminary ruling September 13, 2012.

A–570–868: Folding Metal Tables and Chairs From the People's Republic of China

Requestor: Lifetime Products, Inc.; its 34-inch square fold-in-half tables with model number 80243 and 37-inch square fold-in-half tables with model numbers 80100 and 280011 are not within the scope of the antidumping duty order; July 3, 2012.

A–570–886 Polyethylene Retail Carrier Bags From the People's Republic of China

Requestor: Bunzl Distribution USA, Inc.; its ice bag is not within the scope of the antidumping duty order; July 6, 2012.

A–570–899: Certain Artist Canvas From the People's Republic of China

Requestor: Ningbo Conda Imp & Exp Company Ltd.; artist canvases woven and primed in India, which are subsequently cut, stretched, framed, and packaged in the PRC before exportation to the United States are not within the antidumping duty order; July 6, 2012.

A–570–910/C–570–911: Circular Welded Carbon Quality Steel Pipe From the People's Republic of China

Requestor: LDA Incopordo; electrical rigid metal steel conduits are not within the scope of the antidumping and countervailing duty orders; July 2, 2012.

A–570–912/C–50–913: Certain New Pneumatic Off-the-Road Tires From the People's Republic of China

Requestor: Igloo Products Corp. (''Igloo''); Igloo's new pneumatic tires with an overall 5-inch rim diameter are not within the scope of the antidumping and countervailing duty orders; September 24, 2012.

A–570–918: Steel Wire Garment Hangers From The People's Republic of China

Requestor: PetEdge Inc.; steel wire Canine Pet Fashion Hangers, with dog-shaped, rubber tipped hooks, are not within the scope of the antidumping duty order; August 2, 2012.

A–570–967/C–570–968: Aluminum Extrusions From the People's Republic of China

Requestor: A.O. Smith Corporation; water heater anodes are not within the scope of the antidumping and countervailing duty orders; preliminary ruling July 2, 2012.

A–570–967/C–570–968: Aluminum Extrusions From the People's Republic of China

Requestor: UQM Technologies Inc.; inner and outer motor cases are within the scope of the antidumping and countervailing duty orders; July 6, 2012.

A–570–967/C–570–968: Aluminum Extrusions From the People's Republic of China

Requestor: Electrolux North America, Inc., Electrolux Home Products, Inc. and Electrolux Major Appliances; certain fin evaporator systems (''FESs'') are within the scope of the antidumping and countervailing duty orders; July 13, 2012.

[1] *See* 19 CFR 351.225(o).

[2] *See Notice of Scope Rulings*, 77 FR 52313 (August 29, 2012).

A–570–967/C–570–968: Aluminum Extrusions From the People's Republic of China

Requestor: J.A. Hancock Co., Inc.; Two specific models of unassembled geodesic structure kits (the 11.5-foot radius dome and the 8-foot radius dome) are within the scope of the antidumping and countervailing duty orders; July 17, 2012.

A–570–967/C–570–968: Aluminum Extrusions From the People's Republic of China

Requestor: Ameristar Fence Products; its kitted fence products are within the scope of the antidumping and countervailing duty orders; August 15, 2012.

A–570–967/C–570–968: Aluminum Extrusions From the People's Republic of China

Requestor: (Construction Specialties Inc.); certain Solarmotion controllable sunshades are not within the scope of the antidumping and countervailing duty orders; August 17, 2012.

A–570–967/C–570–968: Aluminum Extrusions From the People's Republic of China

Requestor: Sinobec Resources LLS; certain aluminum rails for showers and carpets are not within the scope of the antidumping and countervailing duty orders; September 6, 2012.

A–570–967/C–570–968: Aluminum Extrusions From the People's Republic of China

Requestor: Innovative Controls Inc.; certain side mount valve controls are not within the scope of the antidumping and countervailing duty orders; preliminary ruling September 24, 2012.

A–570–970/C–570–971: Multilayered Wood Flooring From the People's Republic of China

Requestor: Zhejiang Lingge; its 0.3 mm product, 1 mm product, and unfinished 1 mm product are not within the scope of the antidumping and countervailing duty orders; July 2, 2012.

Taiwan

A–583–843: Polyethylene Retail Carrier Bags From Taiwan

Requestor: SmileMakers, Inc.; its specialty patient bags are within the scope of the antidumping duty order; July 16, 2012.

Multiple Countries

A–201–837/A–570–954/C–570–955: Certain Magnesia Carbon Bricks From Mexico and the People's Republic of China

Requestor: Fedmet Resources Corporation; its imported magnesia carbon bricks with added alumina are within the scope of the antidumping and countervailing duty orders; July 2, 2012.

A–201–837/A–570–954/C–570–955: Certain Magnesia Carbon Bricks From Mexico and the People's Republic of China

Requestor: Ceramark Technology Inc.; its burned magnesite bricks and burned magnesia dolomite bricks are not within the scope of the antidumping and countervailing duty orders; July 26, 2012.

A–560–823/C–560–824/A–570–958/C–570–959: Coated Paper Suitable for High-Quality Print Graphics Using Sheet-Fed Presses From Indonesia and the People's Republic of China

Requestor: Gold East Paper (Jiangsu) Co. Ltd. (including its subsidiaries Ningbo Zhonghua Paper Co., Ltd. and Ningbo Asia Pulp and Paper Co., Ltd.), Global Paper Solutions, Inc., Pindo Deli Pulp and Paper Mills, PT. Indah Kiat Pulp & Paper Tbk, and Paper Max, Ltd. (collectively ''APP''); (1) APP's Ningbo Fold packaging paperboard, APP's Savvi Coat packaging paperboard, APP's Zenith packaging paperboard with a basis weight of 215 grams per square meter (''gsm''), APP's Sinar Vanda packaging paperboard with a basis weight of 210 gsm, and APP's blue-, grey-, and black-center playing card board which APP exports are within the scope of the antidumping duty and countervailing duty orders; (2) APP's Zenith packaging paperboard (except with a basis weight of 215 gsm) and APP's Sinar Vanda packaging paperboard (except with a basis weight of 210 gsm) which APP exports are not within the scope of the antidumping duty and countervailing duty orders; September 13, 2012.

A–570–922, C–570–923, A–583–842: Raw Flexible Magnets From the People's Republic of China and Taiwan

Requestor: Accoutrements LLC; its mustache magnet is not within the scope of the antidumping duty order; August 7, 2012.

Anticircumvention Determinations Made Between July 1, 2012, and September 30, 2012

Mexico

A–201–830: Carbon and Certain Alloy Steel Wire Rod From Mexico

Requestor: ArcelorMittal USA LLC, Gerdau Ameristeel U.S. Inc, Rocky Mountain Steel, Members of the Wire Rod Producers Coalition and Nucor Corporation (Nucor); shipments of certain alloy steel wire rod with an actual diameter of 4.75 mm to 5.00 mm produced in Mexico and exported to the United States by Deacero S.A. de C.V. are circumventing the antidumping order; September 24, 2012.

People's Republic of China

A–570–863: Honey From the People's Republic of China

Requestor: The American Honey Producers Association and the Sioux Honey Association; blends of honey and rice syrup, regardless of the percentage of honey they contain, are later-developed merchandise that are within the scope of the antidumping duty order; August 21, 2012.

A–570–929: Small Diameter Graphite Electrodes From the People's Republic of China

Requestor: SGL Carbon LLC and Superior Graphite Co.; certain small diameter graphite electrodes (''SDGE'') finished by UK Carbon and Graphite Co., Ltd from PRC-produced artificial graphite rod/unfinished SDGE component inputs are circumventing the antidumping duty order; July 31, 2012.

Russian Federation

A–821–807: Ferrovanadium and Nitrided Vanadium From the Russian Federation

Requestor: AMG Vanadium; Russian vanadium pentoxide imported by the Evraz Group and toll-converted into ferrovanadium in the United States by Bear Metallurgical Corporation prior to sale to unaffiliated customers in the United States is not circumventing the antidumping order; July 30, 2012.

Interested parties are invited to comment on the completeness of this list of completed scope and anticircumvention inquiries. Any comments should be submitted to the Deputy Assistant Secretary for AD/CVD Operations, Import Administration, International Trade Administration, 14th Street and Constitution Avenue NW., APO/Dockets Unit, Room 1870, Washington, DC 20230.

This notice is published in accordance with 19 CFR 351.225(o).

Dated: January 8, 2013.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations .

[FR Doc. 2013–02904 Filed 2–7–13; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC491

Fisheries of the Gulf of Mexico; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR Steering Committee Meeting.

SUMMARY: The SEDAR Steering Committee will meet via webinar. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 31 Steering Committee webinar will be held on February 25, 2013, from 11 a.m. to 1 p.m. EST.

ADDRESSES: Meeting address: The webinar will be held via a GoToWebinar Conference. The webinar is open to members of the public. Those interested in participating should contact Andrea Grabman at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request meeting information at least 24 hours in advance.

SEDAR address: 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: John Carmichael, SEDAR Program Manager; telephone: (843) 571–4366; email: *john.carmichael@safmc.net* or Andrea Grabman, SEDAR Administrative Assistant; telephone: (843) 571–4366; email: *andrea.grabman@safmc.net.*

SUPPLEMENTARY INFORMATION: The South Atlantic, Gulf of Mexico and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions, implemented the Southeast Data, Assessment and Review (SEDAR) process for determining the status of fish stocks in the Southeast Region. Oversight of the SEDAR program is provided by a Steering Committee including representatives of the various partner organizations. The Steering Committee meets regularly to discuss assessment project scheduling and SEDAR policies and procedures.

Items for discussion during this webinar include:

1. Gulf Council 2014 benchmark stocks.
2. Caribbean Council 2013 benchmark stocks.
3. South Atlantic Wreckfish Assessment Timing.
4. SEDAR Procedures Workshop: South Atlantic Shrimp Data.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the SEDAR office (see **ADDRESSES**) at least 10 business days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Dated: February 5, 2013.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2013–02870 Filed 2–7–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC488

Gulf of Mexico Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council will convene a meeting of the Ad Hoc Private Recreational Data Collection Advisory Panel.

DATES: The meeting will convene at 8:30 a.m. and conclude by 4 p.m. on Tuesday, February 26, 2013.

ADDRESSES: The meeting will be held at the Gulf of Mexico Fishery Management Council, 2203 N. Lois Avenue, Suite 1100, Tampa, FL 33607; telephone: (813) 348–1630.

FOR FURTHER INFORMATION CONTACT: Dr. John Froeschke, Fishery Biologist-Statistician; Gulf of Mexico Fishery Management Council; telephone: (813) 348–1630 x235.

SUPPLEMENTARY INFORMATION: The Ad Hoc Private Recreational Data Collection Advisory Panel will meet to discuss mechanisms to improve private recreational fisheries data collection in Gulf of Mexico fisheries. The Panel will help identify methods for improving private recreational angler data collection, potentially using additional data collection programs that would supplement data currently collected through the Marine Recreational Information Program (MRIP). Programs considered must improve the accuracy and timeliness of catch, effort, and discard data for the private recreational sector in the Gulf of Mexico. Preferentially, the considered programs should allow participation in the data collection process by private, recreational anglers. The Advisory Panel will consider new methodologies including potential use of offshore permits, vessel registration information or satellite imagery to improve recreational fishery data. The Advisory Panel will consider the appropriate use and limitation of self-reported fisheries data and evaluate and advise about improvements in communication between MRIP and stakeholders.

Copies of the agenda and other related materials can be obtained by calling (813) 348–1630.

Although other non-emergency issues not on the agenda may come before the Advisory Panel for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal action during this meeting. Actions of the Advisory Panel will be restricted to those issues specifically identified in the agenda and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira at the Council (see

ADDRESSES) at least 5 working days prior to the meeting.

Dated: February 5, 2013.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2013–02868 Filed 2–7–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC490

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The Pacific Fishery Management Council's (Council) will hold a workshop on electronic monitoring in the rationalized groundfish trawl fishery.

DATES: The workshop will be convened Monday, February 25, 2013 at 10 a.m. and adjourn Wednesday, February 27, 2013. Upon completion of business Monday and Tuesday, the workshop will recess for the night, and on Wednesday the workshop will adjourn no later than 2 p.m.

ADDRESSES: The meeting will be held at the Embassy Suites Hotel, Juniper Room, 7900 NE 82nd Ave., Portland, OR 97220.

Council address: Pacific Fishery Management Council, 7700 Ambassador Pl., Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Mr. Jim Seger, Pacific Fishery Management Council; telephone: (503) 820–2280.

SUPPLEMENTARY INFORMATION: The purpose of the workshop is to develop the policy context and identify necessary elements for a thorough Magnuson-Stevens Act (MSA) process to consider possible regulatory changes providing for the use of electronic monitoring to adjust the current 100 percent catch observer coverage requirement in the West Coast groundfish trawl catch share program. Workshop recommendations will be provided to the Council for consideration at its April 2013 meeting.

Although non-emergency issues not contained in the meeting agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt at (503) 820–2280 ext 425 or toll free (1–866) 806–7204 at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: February 5, 2013.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2013–02869 Filed 2–7–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC172

Taking of Marine Mammals Incidental to Specified Activities; Construction at Orcas Island and Friday Harbor Ferry Terminals

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; proposed incidental harassment authorization; request for comments and information.

SUMMARY: NMFS has received a request from the Washington State Department of Transportation (WSDOT) Ferries Division (WSF) for an incidental take authorization to take small numbers of 11 species of marine mammals, by Level B harassment, incidental to proposed construction activities for the replacement of dolphin structures at the Orcas Island and Friday Harbor ferry terminals in Washington State. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an authorization to WSDOT to incidentally take, by harassment, small numbers of marine mammals for a period of 1 year.

DATES: Comments and information must be received no later than March 11, 2013.

ADDRESSES: Comments on the application should be addressed to Michael Payne, Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3225. The mailbox address for providing email comments is *itp.guan@noaa.gov.* NMFS is not responsible for email comments sent to addresses other than the one provided here. Comments sent via email, including all attachments, must not exceed a 10-megabyte file size.

Instructions: All comments received are a part of the public record and will generally be posted to *http://www.nmfs.noaa.gov/pr/permits/incidental.htm* without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

A copy of the application may be obtained by writing to the address specified above or visiting the internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm.* Documents cited in this notice may also be viewed, by appointment, during regular business hours, at the aforementioned address.

FOR FURTHER INFORMATION CONTACT: Shane Guan, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''* * * an

impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

Section 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the U.S. can apply for a one-year authorization to incidentally take small numbers of marine mammals by harassment, provided that there is no potential for serious injury or mortality to result from the activity. Section 101(a)(5)(D) establishes a 45-day time limit for NMFS review of an application followed by a 30-day public notice and comment period on any proposed authorizations for the incidental harassment of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny the authorization.

Summary of Request

On May 25, 2012, WSDOT submitted a request to NOAA requesting an IHA for the possible harassment of small numbers of 11 marine mammal species incidental to construction associated with the replacement of dolphin structures at the Orcas Island and Friday Harbor ferry terminals in Washington State. On July 20, WSDOT submitted a revised IHA application. The action discussed in this document is based on WSDOT's July 20, 2012, IHA application.

Description of the Specified Activity

Dolphins are structures located offshore that are used to guide the ferry into the terminal and hold it in place while docked. There are two types of dolphins common at WSF ferry terminals: Timber and steel. Timber dolphins are older structures, typically constructed of creosote treated pilings lashed together by galvanized steel rope, and reinforced as needed with 13″ plastic/steel core piles. WSF is systematically replacing timber dolphins with steel dolphins avoid future structure failures. Steel dolphins consist of reaction piles with a steel diaphragm, and larger fender piles with fender panels. Fender panels are made of ultra high molecular weight (UHMW) plastic, and act as rub surfaces for the ferry.

The proposed project is to replace a single timber dolphin with a new dolphin at the Orcas Island and two timber dolphins with new steel dolphins at the Friday Harbor Ferry Terminal.

Overview of the Planned Activities

The following construction activities are anticipated for the Orcas terminal:

- Remove one 69-pile dolphin (13-inch timber & plastic/steel-core piles/106 tons of creosote-treated timber) with a vibratory hammer or by direct pull and clamshell removal;
- Vibratory pile drive four 24- or 30-inch (final size to be determined) hollow steel reaction piles and three 36-inch hollow steel fender piles;
- Place precast concrete diaphragm on new dolphin;
- Attach fender panels to new fender piles; and
- Reposition one floating dolphin anchor.

The following construction activities are anticipated for the Friday Harbor terminal:

- Remove one 37-pile dolphin (13-inch timber piles/62 tons of creosote-treated timber) with a vibratory hammer or by direct pull and clamshell removal;
- Vibratory pile drive up to four 24- or 30-inch (final size to be determined) hollow steel reaction piles and one 36-inch hollow steel fender pile;
- Place precast concrete diaphragm on new dolphin;
- Attach fender panel to new fender pile;
- Remove one 102-pile dolphin (13-inch timber and plastic/steel-core piles/166 tons of creosote-treated timber) with a vibratory hammer or by direct pull and clamshell removal;
- Vibratory pile drive up to four 24- or 30-inch (final size to be determined) hollow steel reaction piles and four 36-inch hollow steel fender piles;
- Place precast concrete diaphragm on new dolphin; and
- Attach fender panels to new fender piles.

A total of 334 tons of creosote-treated timbers will be removed from the marine environment. The total mudline footprint of the existing dolphins is 256 square feet (ft^2). The total mudline footprint of the new dolphin will be 95 ft^2, a reduction of 161 ft^2. In addition, the footprint of the new steel dolphins will be more open, allowing fish movement between the piles. The new dolphins will have 20 piles, compared to the existing dolphins, which have 208 tightly clustered piles with no space between them.

In summary, the proposed project involves using a vibratory hammer to remove a total of 175 timber piles and using a vibratory hammer to install a total of 20 steel piles for the new dolphins.

Construction Activity Elements

1. Vibratory Hammer Removal

Vibratory hammer extraction is a common method for removing timber piling. A vibratory hammer is a large mechanical device mostly constructed of steel (weighing 5 to 16 tons) that is suspended from a crane by a cable. It is attached to a derrick and positioned on the top of a pile. The pile is then unseated from the sediments by engaging the hammer, creating a vibration that loosens the sediments binding the pile, and then slowly lifting up on the hammer with the aid of the crane.

Once unseated, the crane will continue to raise the hammer and pull the pile from the sediment. When the pile is released from the sediment, the vibratory hammer is disengaged and the pile is pulled from the water and placed on a barge for transfer upland. Vibratory removal will take approximately 10 to 15 minutes per pile.

2. Direct Pull and Clamshell Removal

Older timber pilings are particularly prone to breaking at the mudline because of damage from marine borers and vessel impacts and must be removed because they can interfere with the installation of new pilings. In some cases, removal with a vibratory hammer is not possible if the pile is too fragile to withstand the hammer force. Broken or damaged piles may be removed by wrapping the piles with a cable and pulling them directly from the sediment with a crane. If the piles break below the waterline, the pile stubs will be removed with a clamshell bucket, a hinged steel apparatus that operates like a set of steel jaws. The bucket will be lowered from a crane and the jaws will grasp the pile stub as the crane pulled up. The broken piling and stubs will be loaded onto the barge for off-site disposal. Clamshell removal will be used only if necessary.

3. Vibratory Hammer Installation

Vibratory hammers are also commonly used in steel pile installation where sediments allow and involve the same vibratory hammer used in pile extraction. The pile is placed into position using a choker and crane, and then vibrated between 1,200 and 2,400 vibrations per minute. The vibrations liquefy the sediment surrounding the pile allowing the pile to penetrate to the required seating depth. The type of vibratory hammer that will be used for the project will likely be an APE 400 King Kong (or equivalent) with a drive force of 361 tons.

Sound Levels from Proposed Construction Activity

As mentioned earlier, the proposed construction project includes vibratory removal of 208, 13-inch timber and plastic-faced piles, and vibratory driving of 20 24-inch, 30-inch and 36-inch hollow steel piling.

No sound level data is available for 13-inch timber and plastic-faced piles. Based on in-water measurements at the WSF Port Townsend Ferry Terminal (Laughlin 2011a), removal of 12-inch timber piles generated 149 to 152 dB re 1 µPa (root-mean-square, or rms) with an overall average rms value of 150 dB re 1 µPa (rms) measured at 16 meters. A worst-case noise level for vibratory removal of 13-inch timber and plastic-faced piles will be 152 dB re 1 µPa (rms) at 16 m.

Based on in-water measurements at the WSF Friday Harbor Ferry Terminal, vibratory pile driving of a 24-inch steel pile generated 162 dB re 1 µPa (rms) measured at 10 meters (Laughlin 2010a).

Based on in-water measurements during a vibratory test pile at the WSF Port Townsend Ferry Terminal, vibratory pile driving of a 30-inch steel pile generated 170 dB re 1 µPa (rms) (overall average), with the highest measured at 174 dB re 1 µPa (rms) measured at 10 meters (Laughlin 2010b). A worst-case noise level for vibratory driving of 30-inch steel piles will be 174 dB re 1 µPa (rms) at 10 m.

Based on in-water measurements at the Port Townsend ferry terminal, vibratory pile driving of a 36″ pile measured at 10 m generated 172 dB re 1 µPa (rms) (overall average), with the highest measured at 177 dB re 1 µPa (rms) (Laughlin 2010b). A worst-case noise level for vibratory driving of 36″ steel piles will be 177 dB re 1 µPa (rms) at 10 m.

While in-air sounds are not applicable to cetaceans, they are to pinnipeds, especially harbor seals when hauled out. No unweighted in-air sound level data is available for 13-inch timber and plastic-faced pile removal, or for 24- or 36-inch vibratory pile driving. Unweighted in-air measurements of vibratory driving of a 30-inch steel pile collected during the 2010 Keystone Ferry Terminal Wingwalls Replacement Project ranged from 95–97.8 dB re 20 µPa (rms) at 50 ft. (Laughlin 2010b). Removal of 13-inch pile in-air noise levels will be conservatively assumed to be the same as pile

Using practical spreading model to calculate sound propagation loss, Table 1 provides the estimated distances where the received underwater sound levels drops to 120 dB re 1 µPa (rms), which is the threshold that currently used for determining Level B behavioral harassment (see below) from non-impulse noise sources based on measurements of different pile sizes.

TABLE 1—ESTIMATED DISTANCES WHERE VIBRATORY PILE DRIVING RECEIVED SOUND LEVELS DROP TO 120 dB re 1 µPa BASED ON MEASUREMENTS OF DIFFERENT PILE SIZES

Pile size (inch)	Measured source levels	Distance to 120 dB re 1 µPa (rms) (km)
13	152 dB re 1 µPa (rms) @ 16 m	2.2
24	162 dB re 1 µPa (rms) @ 10 m	6.3
30	174 dB re 1 µPa (rms) @ 10 m	39.8
36	177 dB re 1 µPa (rms) @ 10 m	63.1

However, land mass is intersected before these distances are reached, except for vibratory pile removal. For the Orcas terminal, land is intersected at a maximum of 3.5 km (2.2 miles). For the Friday Harbor terminal, land is intersected at a maximum of 4.7 km (2.9 miles).

For airborne noise, currently NMFS uses an in-air noise disturbance threshold of 90 dB re 20 µPa (rms) (unweighted) for harbor seals, and 100 dB re 20 µPa (rms) (unweighted) for all other pinnipeds. Using the above aforementioned measurement of 97.8 dB re 20 µPa (rms) @ 50 ft, and attenuating at 6 dBA per doubling distance, in-air noise from vibratory pile removal and driving will attenuate to the 90 dB re 20 µPa (rms) within approximately 37 m, and the 100 dB re 20 µPa (rms) within approximately 12 m.

Dates, Duration, and Region of Activity

In-water construction is planned to take place between September 1, 2013, and February 15, 2014. The on-site work will last approximately 8 weeks with actual pile removal and driving activities taking place approximately 25% of that time.

The number of days it will take to remove and install the pilings largely depends on the condition of the piles being removed and the difficulty in penetrating the substrate during pile installation. Duration estimates of each of the pile removal and pile driving elements follow:

- The daily construction window for pile removal or driving will begin no sooner than 30 minutes after sunrise to allow for initial marine mammal monitoring, and will end at sunset (or soon after), when visibility decreases to the point that effective marine mammal monitoring is not possible.
- Vibratory pile removal of the existing timber/plastic-faced piles will take approximately 10 to 15 minutes per pile. Vibratory removal will take less time than driving, because piles are vibrated to loosen them from the soil, and then pulled out with the vibratory hammer turned off. Assuming the worst case of 15 minutes per pile (with no direct pull or clamshell removal), removal of 69 piles at the Orcas terminal will take 17.2 hours over three days of pile removal. Removal of 139 piles at the Friday Harbor terminal will take 34.75 hours over five days of pile removal.
- Vibratory pile driving of the steel piles will take approximately 20 minutes per pile, with three to five piles installed per day. Assuming 20 minutes per pile, and three piles per day, driving of 7 piles at the Orcas terminal will take 2.3 hours over 2 days. Driving of 13 piles at the Friday Harbor terminal will take 4.3 hours over 5 days.

The total worst-case time for pile removal is 7 days, and for pile installation 10 days. The actual number of pile-driving days is expected to be less.

All work at the Orcas terminal will occur in water depths between −24.6 and −31.6 feet MLLW. At the Friday Harbor terminal all work will occur between −30 and −34 feet MLLW.

Description of Marine Mammals in the Area of the Specified Activity

The marine mammal species under NMFS jurisdiction most likely to occur in the proposed construction area include Pacific harbor seal (*Phoca vitulina richardsi*), California sea lion (*Zalophus californianus*), northern elephant seal (*Mirounga angustirostris*),

Steller sea lion (*Eumetopias jubatus*), harbor porpoise (*Phocoena phocoena*), Dall's porpoise (*Phocoenoides dalli*), Pacific white-sided dolphin (*Lagenorhynchus obliquidens*), killer whale (*Orcinus orca*), gray whale (*Eschrichtius robustus*), humpback whale (*Megaptera novaeangliae*), and minke whale (*Balaenoptera acutorostra*).

General information on the marine mammal species found in California waters can be found in Caretta *et al.* (2011), which is available at the following URL: *http://www.nmfs.noaa.gov/pr/pdfs/sars/po2010.pdf*. Refer to that document for information on these species. Specific information concerning these species in the vicinity of the proposed action area is provided below.

Harbor Seal

Harbor seals are members of the true seal family (Phocidae). For management purposes, three separate harbor seal stocks are recognized along the west coast of the continental U.S. (Boveng 1988): (1) Inland waters of Washington State (including Hood Canal, Puget Sound, Georgia Basin and the Strait of Juan de Fuca out to Cape Flattery), (2) outer coast of Oregon and Washington, and (3) California (Carretta *et al.* 2007a). Pupping seasons vary by geographic region. For the San Juan Island region, pups are born from June through August, and in southern Puget Sound pups are born from mid-July through September (Jeffries *et al.* 2000). However, recent observations by the Washington Department of Fish and Wildlife (WDFW) biologists reveal that harbor seal pupping seasons in San Juan Island and Georgia Basin extend from June 1 to October 1 (WSDOT 2012). After October 1 all pups in the inland waters of Washington are weaned.

Of the four pinniped species that occur within the region of activity, harbor seals are the most numerous and the only one that breeds in the inland marine waters of Washington (Calambokidis and Baird 1994). In 1999, Jeffries *et al.* (2003) recorded a mean count of 9,550 harbor seals in Washington's inland marine waters, and estimated the total population to be approximately 14,600 animals (including the Strait of Juan de Fuca). The population across Washington increased at an average annual rate of 10 percent between 1991 and 1996 (Jeffries *et al.* 1997) and is thought to be stable (Jeffries *et al.* 2003). The Whale Museum/Marine Mammal Stranding Network estimates that approximately 4,000 seals are present in the San Juan Islands (Whale Museum 2012a).

Within the inland waters of Washington, there are numerous harbor seal haulout sites located on intertidal rocks, reefs, and islands. The nearest known haulout sites to the Orcas Island ferry terminal are Blind Island Rocks and Blind Island (approximately 1.2 and 1.4 km south of the Orcas terminal) and Bell Island (approximately 2.7 km west of the Orcas terminal). The nearest known haulout sites to the Friday Harbor ferry terminal are the intertidal rocks NE of Point George on Shaw Island (approximately 4 km and 4.7 km NE of the Friday Harbor terminal) offshore of Shaw Island (Figure 3–2). The number of harbor seals using these haulouts is less than 100 per haulout (WDFW 2000). The level of use of this haulout during the fall and winter is unknown, but is expected to be much less as air temperatures become colder than water temperatures resulting in seals in general hauling out less (WSDOT 2012).

Harbor seals are not considered to be ''depleted'' under the MMPA or listed as ''threatened'' or ''endangered'' under the ESA. The stock is also considered within its Optimum Sustainable Population level (Jeffries *et al.* 2003).

California Sea Lion

NMFS recognizes three stocks of California sea lion based on their geographic distribution: (1) The U.S. stock begins at the U.S./Mexico border and extends northward into Canada; (2) the Western Baja California stock extends from the U.S./Mexico border to the southern tip of the Baja California Peninsula; and (3) the Gulf of California stock, which includes the Gulf of California from the southern tip of the Baja California peninsula and across to the mainland and extends to southern Mexico (Lowry *et al.* 1992). California sea lions in the Washington State belong to the U.S. stock.

The U.S. stock was estimated at 238,000 in the 2010 Stock Assessment Report (SAR) and may be at carrying capacity, although more data are needed to verify that determination (Carretta *et al.* 2007a). The number of California sea lions in the San Juan Islands and the adjacent Strait of Juan de Fuca totaled fewer than 3,000 in the mid-1980s (Bigg 1985; Gearin *et al.* 1986). In 1994, it was reported that the number of sea lions had stabilized or decreased in some areas (Gearin *et al.* 1988; Calambokidis and Baird 1994). More recently, 3,000 to 5,000 animals are estimated to move into northwest waters (both Washington and British Columbia) during the fall (September) and remain until the late spring (May) when most return to breeding rookeries in California and Mexico (Jeffries *et al.* 2000; WSDOT 2012). Peak counts of over 1,000 animals have been made in Puget Sound (Jeffries *et al.* 2000).

In Washington, California sea lions use haulout sites within all inland water regions (Jeffries *et al.* 2000). The nearest documented California sea lion haulout sites to the Orcas and Friday Harbor terminals are intertidal rocks and reef areas around Trial Island and Race Rocks near Victoria, B.C. (approximately 32/24 km west of the Orcas/Friday Harbor terminals, respectively). The number of California sea lions using these haulouts is less than 100 per haulout (WDFW 2000). Small numbers of sea lions may occasionally use navigation buoys in the San Juan Islands (WDFW 2000).

California sea lions were unknown in Puget Sound until approximately 1979 (Steiger and Calambokidis 1986). Everitt *et al.* (1980) reported the initial occurrence of large numbers at Port Gardner, just north of Everett (in northern Puget Sound), in the spring of 1979. The number of California sea lions using this area today number around 1,000 (WSDOT 2012). This haulout remains the largest in the state for sea lions in general and for California sea lions specifically (WSDOT 2012). Similar sightings and increases in numbers were documented throughout the region after the initial sighting in 1979 (Steiger and Calambokidis 1986), including urbanized areas such as Elliot Bay near Seattle and heavily used areas of central Puget Sound (Gearin *et al.* 1986). The movement of California sea lions into Puget Sound could be an expansion in range of a growing population (Steiger and Calambokidis 1986).

California sea lions do not avoid areas with heavy or frequent human activity, but rather may approach certain areas to investigate. This species typically does not flush from a buoy or haulout if approached.

California sea lions are not listed as endangered or threatened under the ESA or as depleted under the MMPA. They are not considered a strategic stock under the MMPA.

Northern Elephant Seal

Northern elephant seals are the largest pinniped found in Washington marine waters. Populations of northern elephant seals in the U.S. and Mexico are the result of a few hundred survivors remaining after hunting nearly led to the species' extinction (Stewart *et al.* 1994). Elephant seals present in the region of activity are considered part of the California breeding stock (Carretta *et al.* 2007a). Northern elephant seals breed

and give birth primarily on islands off of California and Mexico from December through March (Stewart and Huber 1993; Carretta *et al.* 2007a). Typically, juveniles form new colonies and one or more females join to result in new haulout and rookery sites (Bonnell *et al.* 1991).

Northern elephant seal abundance estimates for inland Washington waters are not available due to the infrequency of sightings and the low numbers encountered (WSDOT 2012). Rough estimates suggest less than 100 individuals use the area annually (WSDOT 2012). Breeding rookeries are located on beaches and islands in California and Mexico (Jeffries *et al.* 2000). Historically, after their winter breeding season and annual molt cycles, individuals dispersed northward along the Oregon and Washington coasts and were present only on a seasonal basis. However, a few individuals are now found in Washington inland waters year-round.

Haulout areas are not as predictable as for the other species of pinnipeds. In total, WDFW has identified seven haulout sites in inland Washington waters used by this species. A few individuals use beaches at Protection Island (52/46 km south of the Orcas/Friday Harbor terminals, respectively) and Smith/Minor Islands (32/27 km south of the Orcas/Friday Harbor terminals) (WDFW 2000). Typically these sites have only two to ten adult males and females, but pupping has occurred at all of these sites over the past ten years (WSDOT 2012). A single individual has been observed hauled out at American Camp on San Juan Island (NPS 2012), and at Shaw Island County Park on Shaw Island (Miller 2012).

Northern elephant seals are not listed as endangered or threatened under the ESA or as depleted under the MMPA.

Steller Sea Lion

Steller sea lions comprise two recognized management stocks (eastern and western), separated at 144° W longitude (Loughlin 1997). Only the eastern stock is considered here because the western stock occurs outside of the geographic area of the proposed activity. Breeding rookeries for the eastern stock are located along the California, Oregon, British Columbia, and southeast Alaska coasts, but not along the Washington coast or in inland Washington waters (Angliss and Outlaw 2007). Steller sea lions primarily use haulout sites on the outer coast of Washington and in the Strait of Juan de Fuca along Vancouver Island in British Columbia. Only sub-adults or non-breeding adults may be found in the inland waters of Washington (Pitcher *et al.* 2007).

The eastern stock of Steller sea lions is estimated to be between 48,519 and 54,989 individuals based on 2002 through 2005 pup counts (Angliss and Outlaw 2007). Washington's estimate including the outer coast is 651 individuals (non-pups only) (Pitcher *et al.* 2007). However, recent estimates are that 1,000 to 2,000 individuals enter the Strait of Juan de Fuca during the fall and winter months (WSDOT 2012).

Steller sea lions in Washington State decline during the summer months, which correspond to the breeding season at Oregon and British Columbia rookeries (approximately late May to early June) and peak during the fall and winter months (Jeffries *et al.* 2000). A few Steller sea lions can be observed year-round in Puget Sound/Georgia Basin although most of the breeding age animals return to rookeries in the spring and summer.

For Washington inland waters, Steller sea lion abundances vary seasonally with a minimum estimate of 1,000 to 2,000 individuals present or passing through the Strait of Juan de Fuca in fall and winter months (WSDOT 2012, citing S. Jeffries pers. comm. 2008). However, the number of haulout sites has increased in recent years. Haulouts in the San Juan Islands include Green Point on Speiden Island (12/13 km northwest of the Orcas/Friday Harbor terminals, respectively), North Peapod Rock (15/23 km northeast of the Orcas/Friday Harbor terminals, respectively), Bird Rocks (18/19 km southeast of the Orcas/Friday Harbor terminals, respectively) and Whale Rock (17/11 km south of the Orcas/Friday Harbor terminals, respectively) (NMFS 2012).

Steller sea lions were listed as threatened range-wide under the ESA on November 26, 1990 (55 FR 49204). After division into two stocks, the western stock was listed as endangered under the ESA on May 4, 1997 and the eastern stock remained classified as threatened (62 FR 24345). In 2006 the NMFS Steller sea lion recovery team proposed removal of the eastern stock from listing under the ESA based on its annual rate of increase of approximately 3% since the mid-1970s.

On August 27, 1993, NMFS published a final rule designating critical habitat for the Steller sea lion (NMFS 1993). No critical habitat has been designated in Washington (NMFS 1993). Critical habitat is associated with breeding and haulout areas in Alaska, California, and Oregon (NMFS 1993).

Steller sea lions are listed as depleted under the MMPA. Both stocks are thus classified as strategic.

Harbor Porpoise

In the Northwest U.S., harbor porpoises are divided into two stocks: (1) The Washington Inland Waters Stock, and (2) the Oregon/Washington Coast Stock (Carretta *et al.* 2007b). The Washington Inland Waters Stock occurs in waters east of Cape Flattery (Strait of Juan de Fuca, San Juan Island Region, and Puget Sound). The Oregon/Washington Coast Stock extends from Cape Flattery, Washington south to Cape Blanco, Oregon. Although harbor porpoises have been spotted in deep water, they tend to remain in shallower shelf waters (<150 m) where they are most often observed in small groups of one to eight animals (Baird 2003).

Little information regarding food habits of the harbor porpoise is available for British Columbia or inland Washington waters (Hall 2004). What prey species have been documented include juvenile blackbelly eelpout, opal squid, Pacific herring, walleye pollock, Pacific hake, eulachon, and Pacific sanddab (Walker *et al.* 1998). Based on the results from Walker *et al.* (1998) and Hall (2004), harbor porpoises in British Columbia and Washington are opportunistic feeders, with prey species varying based on seasonal abundance. They also likely alter their spatial and temporal distributions based on prey availability.

The Washington Inland Waters Stock mean abundance estimate based on 2002 and 2003 aerial surveys conducted in the Strait of Juan de Fuca, San Juan Islands, Gulf Islands, and Strait of Georgia is 10,682 harbor porpoises (Carretta *et al.* 2007b). Abundance estimates of harbor porpoises for the Strait of Juan de Fuca and the San Juan Islands in 1991 were approximately 3,300 animals (Calambokidis *et al.* 1993). Harbor porpoises were once considered common in southern Puget Sound (Scheffer and Slipp 1948); however, there has been a significant decline in sightings within southern Puget Sound since the 1940s (Everitt *et al.* 1980; Calambokidis *et al.* 1985, 1992; Carretta *et al.* 2007b).

Virtually no data are available to assess population trends in Puget Sound (Scheffer and Slipp 1948; Everitt *et al.* 1980; Calambokidis *et al.* 1985, 1992; Calambokidis and Baird 1994). No harbor porpoises were observed within Puget Sound proper during comprehensive harbor porpoise surveys (Osmek *et al.* 1994) or Puget Sound Ambient Monitoring Program (PSAMP) surveys conducted in the 1990s. Declines were attributed to gill-net fishing, increased vessel activity, contaminants, and competition with

Dall's porpoise. However, Puget Sound populations appear to be rebounding with increased sightings in central (Carretta *et al.* 2007b) and southern (WDFW 2008) Puget Sound.

Harbor porpoises are common in the Strait of Juan de Fuca and south into Admiralty Inlet, especially during the winter, but are not at all common south of Admiralty Inlet. Harbor porpoises occur year-round and breed in the waters around the San Juan Archipelago and north into Canadian waters (Calambokidis and Baird 1994). Little information exists on harbor porpoise movements and stock structure near the Orcas and Friday Harbor terminals, although it is suspected that in some areas harbor porpoises migrate (based on seasonal shifts in distribution). For instance Hall (WSDOT 2012) found harbor porpoises off Canada's southern Vancouver Island to peak during late summer, while WDFW's PSAMP data show peaks in Washington water to occur during the winter. Still, no additional evidence exists for migrations in the inland waters of Washington or British Columbia (Calambokidis and Baird 1994; Rosel *et al.* 1995). Hall (WSDOT 2012) found that the frequency of sighting of harbor porpoises decreased with increasing depth beyond 150 m with the highest numbers observed at water depths ranging from 61 to 100 m.

The harbor porpoise is not listed under the ESA and is classified as non-depleted under the MMPA.

Dall's Porpoise

Dall's porpoise occur in the North Pacific Ocean and is divided into two stocks: (1) California, Oregon, and Washington; and (2) Alaska (Carretta *et al.* 2007b). The segment of the population within Washington's inland waters was last assessed in 1996 by aerial surveys (Calambokidis *et al.* 1997). During a ship line-transect survey conducted in 2005, Dall's porpoise was the most abundant cetacean species off the Oregon and Washington coast (Forney 2007). Dall's porpoises are migratory and appear to have predictable seasonal movements driven by changes in oceanographic conditions (Green *et al.* 1992, 1993). This species is commonly seen in shelf, slope, and offshore waters (Carretta *et al.* 2007b).

The California, Oregon, and Washington stock mean abundance estimate of Dall's porpoises based on 2001 and 2005 ship surveys is 57,549 (Barlow 2003; Forney 2007). Within the inland waters of Washington and British Columbia, this species is most abundant in the Strait of Juan de Fuca east to the San Juan Islands. In 1994, Calambokidis and Baird (1994) estimated the Juan de Fuca population at 3,015 animals and the San Juan Island population at about 133 animals. Calambokidis *et al.* (1997) estimated that 900 animals annually inhabited Washington's inland waters. Prior to the 1940s, Dall's porpoises were not reported in Puget Sound.

Dall's porpoises are migratory and appear to have predictable seasonal movements driven by changes in oceanographic conditions (Green *et al.* 1992, 1993), and are most abundant in Puget Sound during the winter (Nysewander *et al.* 2005; WDFW 2008). Despite their migrations, Dall's porpoises occur in all areas of inland Washington at all times of year (WSDOT 2012 citing J. Calambokidis pers. comm. 2006), but with different distributions throughout Puget Sound from winter to summer.

Dall's porpoise are not listed under the ESA and is classified as non-depleted under the MMPA.

Pacific White-Sided Dolphin

Pacific white-sided dolphins are occasionally seen in the northernmost part of the Strait of Georgia and in western Strait of Juan de Fuca, but are generally only rare visitors to this area (Calambokidis and Baird 1994). This species is rarely seen in Puget Sound. Pacific white-sided dolphins have been documented primarily in deep, off-shore areas (Green *et al.* 1992, 1993; Calambokidis *et al.* 2004a).

The California, Oregon, and Washington stock mean abundance estimate based on the two most recent ship surveys is 25,233 Pacific white-sided dolphins (Forney 2007). This abundance estimate is based on two summer/autumn shipboard surveys conducted within 300 nautical miles of the coasts of California, Oregon, and Washington in 2001 and 2005 (Barlow 2003, Forney 2007). Surveys in Oregon and Washington coastal waters resulted in an estimated abundance of 7,645 animals (Forney 2007).

Fine-scale surveys in Olympic Coast slope waters and the Olympic Coast National Marine Sanctuary resulted in an estimated abundance of 1,196 and 1,432 animals, respectively (Forney 2007), but there are no population estimates for Washington's inland waters. During aerial surveys of Washington inland waters conducted under WDFW's PSAMP program between 1992 and 2008, only a single group of three Pacific white-sided dolphins was observed (summer 1995 in the Strait of Juan de Fuca), although Osborne *et al.* (1988) states they are regularly reported in the Strait of Juan de Fuca and Haro Strait. There are few records for Puget Sound.

Pacific white-sided dolphins have been reported to be regular summer and fall inhabitants of the Strait of Juan de Fuca and San Juan Islands (specifically Haro Strait) (Osborne *et al.* 1988), but extremely rare in Puget Sound.

Pacific white-sided dolphins are not listed under the ESA and are classified as non-depleted under the MMPA.

Killer Whale

Two sympatric ecotypes of killer whales are found within the proposed activity area: transient and resident. These types vary in diet, distribution, acoustic calls, behavior, morphology, and coloration (Baird 2000; Ford *et al.* 2000). The ranges of transient and resident killer whales overlap; however, little interaction and high reproductive isolation occurs among the two ecotypes (Barrett-Lennard 2000; Barrett-Lennard and Ellis 2001; Hoelzel *et al.* 2002). Resident killer whales are primarily piscivorous, whereas transients primarily feed on marine mammals, especially harbor seals (Baird and Dill 1996). Resident killer whales also tend to occur in larger (10 to 60 individuals), stable family groups known as pods, whereas transients occur in smaller (less than 10 individuals), less structured pods.

One stock of transient killer whale, the West Coast Transient stock, occurs in Washington State. West Coast transients primarily forage on harbor seals (Ford and Ellis 1999), but other species such as porpoises and sea lions are also taken (NMFS 2008a).

Two stocks of resident killer whales occur in Washington State: the Southern Resident and Northern Resident stocks. Southern Residents occur within the activity area, in the Strait of Juan de Fuca, Strait of Georgia, and in coastal waters off Washington and Vancouver Island, British Columbia (Ford *et al.* 2000). Northern Residents occur primarily in inland and coastal British Columbia and Southeast Alaska waters and rarely venture into Washington State waters. Little interaction (Ford *et al.* 2000) or gene flow (Barrett-Lennard 2000; Barrett-Lennard and Ellis 2001; Hoelzel *et al.* 2004) is known to occur between the two resident stocks.

The West Coast Transient stock, which includes individuals from California to southeastern Alaska, was estimated to have a minimum number of 354 (NMFS 2010b). Trends in abundance for the West Coast Transients were unavailable in the most recent stock assessment report (Angliss and Outlaw 2007).

The Southern Resident stock was first recorded in a census in 1974, at which time the population comprised 71 whales. This population peaked at 97 animals in 1996, declined to 79 by 2001 (Center for Whale Research 2011), and then increased to 89 animals by 2006 (Carretta *et al.* 2007a). As of 2012, the population collectively numbers 84 individuals (Whale Museum 2012b).

Both West Coast Transient and the Southern Resident stocks are found within Washington inland waters. Individuals of both forms have long-ranging movements and thus regularly leave the inland waters (Calambokidis and Baird 1994).

Killer whales are protected under the MMPA of 1972. The West Coast Transient stock is not designated as depleted under the MMPA or listed as ''threatened or ''endangered'' under the ESA. The Southern Resident stock is listed as an endangered distinct population segment (DPS) under the ESA. On November 29, 2006, NMFS published a final rule designating critical habitat for the Southern Resident killer whale DPS (71 FR 69054). Both Puget Sound and the San Juan Islands are designated as core areas of critical habitat under the ESA, but areas less than 20 feet deep relative to extreme high water are not designated as critical habitat (71 FR 69054). A final recovery plan for southern residents was published in January of 2008 (NMFS 2008a).

Gray Whale

Gray whales are recorded in Washington waters during feeding migrations between late spring and autumn with occasional sightings during winter months (Calambokidis *et al.* 1994, 2002; Orca Network 2011).

Early in the 20th century, it is believed that commercial hunting for gray whales reduced population numbers to below 2,000 individuals (Calambokidis and Baird 1994). After listing of the species under the ESA in 1970, the number of gray whales increased dramatically resulting in their delisting in 1994. Population surveys since the delisting estimate that the population fluctuates at or just below the carrying capacity of the species (~26,000 individuals) (Rugh *et al.* 1999; Calambokidis *et al.* 1994; Angliss and Outlaw 2007).

Within Washington waters, gray whale sightings reported to Cascadia Research and the Whale Museum between 1990 and 1993 totaled over 1,100 (Calambokidis *et al.* 1994). Forty-eight individual gray whales were observed in Puget Sound and Hood Canal in 2004 and 2005 (Calambokidis 2007). Abundance estimates calculated for the small regional area between Oregon and southern Vancouver Island, including the San Juan Area and Puget Sound, suggest there were 137 to 153 individual gray whales from 2001 through 2003 (Calambokidis *et al.* 2004b).

Gray whales migrate within 5 to 43 km of the coast of Washington during their annual north/south migrations (Green *et al.* 1995). Gray whales migrate south to Baja California where they calve in November and December, and then migrate north to Alaska from March through May (Rice *et al.* 1984; Rugh *et al.* 2001) to summer and feed. A very few gray whales are observed in Washington inland waters between the months of September and January, with peak numbers of individuals from March through May (WSDOT 2012 citing J. Calambokidis pers. comm. 2007). Peak months of gray whale observations in the area of activity occur outside the proposed work window of September through February. The average tenure within Washington inland waters is 47 days and the longest stay was 112 days (WSDOT 2012 citing J. Calambokidis pers. comm. 2007).

Although typically seen during their annual migrations on the outer coast, a regular group of gray whales annually comes into the inland waters at Saratoga Passage and Port Susan from March through May to feed on ghost shrimp (Weitkamp *et al.* 1992). During this time frame they are also seen in the Strait of Juan de Fuca, the San Juan Islands, and areas of Puget Sound, although the observations in Puget Sound are highly variable between years (Calambokidis *et al.* 1994, 2002). In northern Puget Sound between Admiralty Inlet and the Edmonds/Kingston Ferry route, sightings of gray whales are more common and regular (Calambokidis *et al.* 1994, Orca Network 2011), although most all these sightings occur between March and May. Between January 2005 and February 2012, the Orca Network logged 13 sightings of gray whales in the September to February window proposed for the Orcas and Friday Harbor Ferry Terminal projects.

The Eastern North Pacific stock of gray whales was removed from listing under the ESA in 1994 after a 5-year review by NOAA Fisheries (Angliss and Outlaw 2007). In 2001 NOAA Fisheries received a petition to relist the stock under the ESA, but it was determined that there was not sufficient information to warrant the petition (Angliss and Outlaw 2007).

Humpback Whale

Few humpback whales have been seen in Puget Sound, but more frequent sightings occur in the Strait of Juan de Fuca and near the San Juan Islands. Most sightings are in spring and summer. Historically, humpback whales were common in inland waters of Puget Sound and the San Juan Islands (Calambokidis *et al.* 2002). In the early part of this century, there was a productive commercial hunt for humpbacks in Georgia Strait that was probably responsible for their long disappearance from local waters (Osborne *et al.* 1988). Since the mid-1990s, sightings in Puget Sound have increased. Between 1996 and 2001, Calambokidis *et al.* (2002) recorded only six individuals south of Admiralty Inlet. Between January 2005 and February 2012, the Orca Network logged 19 sightings of humpbacks in the September to February window proposed for the Orcas and Friday Harbor Ferry Terminal projects.

Humpback whales are listed as endangered under the ESA and depleted under the MMPA.

Minke Whale

The California/Oregon/Washington stock of minke whale is considered a resident stock, which is unlike the other Northern Pacific stocks of this species (NMFS 2008b). This stock includes minke whales within the inland Washington waters of Puget Sound and the San Juan Islands (Dorsey *et al.* 1990; Carretta *et al.* 2007b).

The number of minke whales in the California/Oregon/Washington stock is estimated between 500 and 1,015 individuals (Barlow 2003; Carretta *et al.* 2007b; NMFS 2008b). Over a 10-year period, 30 individuals were photographically identified in the transboundary area around the San Juan Islands and demonstrated high site fidelity (Dorsey *et al.* 1990; Calambokidis and Baird 1994). In a single year, up to 19 individuals were photographically identified from around the San Juan Islands (Dorsey *et al.* 1990).

Minke whales are reported in Washington inland waters year-round, although few are reported in the winter (Calambokidis and Baird 1994). Minke whales are relatively common in the San Juan Islands and Strait of Juan de Fuca (especially around several of the banks in both the central and eastern Strait), but are relatively rare in Puget Sound. Infrequent observations occur in Puget Sound south of Admiralty Inlet (Orca Network 2011). Between January 2005 and February 2012, the Orca

Network logged 42 sightings of minke in the September to February window proposed for the Orcas and Friday Harbor Ferry Terminal projects.

Minke whales are not listed under the ESA and are classified as non-depleted under the MMPA.

Potential Effects of the Specified Activity on Marine Mammals

WSDOT and NMFS determine that open-water pile driving and pile removal associated with the construction activities at Orcas Island and Friday Harbor Ferry Terminal has the potential to result in behavioral harassment of marine mammal species and stocks in the vicinity of the proposed activity.

Marine mammals exposed to high intensity sound repeatedly or for prolonged periods can experience hearing threshold shift (TS), which is the loss of hearing sensitivity at certain frequency ranges (Kastak *et al.* 1999; Schlundt *et al.* 2000; Finneran *et al.* 2002; 2005). TS can be permanent (PTS), in which case the loss of hearing sensitivity is unrecoverable, or temporary (TTS), in which case the animal's hearing threshold will recover over time (Southall *et al.* 2007). Since marine mammals depend on acoustic cues for vital biological functions, such as orientation, communication, finding prey, and avoiding predators, marine mammals that suffer from PTS or TTS will have reduced fitness in survival and reproduction, either permanently or temporarily. Repeated noise exposure that leads to TTS could cause PTS.

Experiments on a bottlenose dolphin (*Tursiops truncates*) and beluga whale (*Delphinapterus leucas*) showed that exposure to a single watergun impulse at a received level of 207 kPa (or 30 psi) peak-to-peak (p-p), which is equivalent to 228 dB (p-p) re 1 μPa, resulted in a 7 and 6 dB TTS in the beluga whale at 0.4 and 30 kHz, respectively. Thresholds returned to within 2 dB of the pre-exposure level within 4 minutes of the exposure (Finneran *et al.* 2002). No TTS was observed in the bottlenose dolphin. Although the source level of pile driving from one hammer strike is expected to be much lower than the single watergun impulse cited here, animals being exposed for a prolonged period to repeated hammer strikes could receive more noise exposure in terms of SEL than from the single watergun impulse (estimated at 188 dB re 1 μPa^2-s) in the aforementioned experiment (Finneran *et al.* 2002).

Currently, NMFS considers that repeated exposure to received noise levels at 180 dB and 190 dB re 1 μPa (rms) could lead to TTS in cetaceans and pinnipeds, respectively. For the proposed dolphin replacement work at Orcas Island and Friday Harbor Ferry Terminal, only vibratory pile driving would be used. Noise levels measured near the source of vibratory hammers (10 m and 16 m from the source, see above) are much lower than the 180 dB re 1 μPa (rms). Therefore, it is very unlikely that any marine mammals would experience TTS or PTS as a result of noise exposure to WSDOT's proposed construction activities at Orcas Island and Friday Harbor Ferry Terminal.

In addition, chronic exposure to excessive, though not high-intensity, noise could cause masking at particular frequencies for marine mammals that utilize sound for vital biological functions (Clark *et al.* 2009). Masking can interfere with detection of acoustic signals such as communication calls, echolocation sounds, and environmental sounds important to marine mammals. Therefore, under certain circumstances, marine mammals whose acoustical sensors or environment are being severely masked could also be impaired from maximizing their performance fitness in survival and reproduction.

Masking occurs at the frequency band which the animals utilize. Therefore, since noise generated from in-water vibratory pile driving and removal is mostly concentrated at low frequency ranges, it may have less effect on high frequency echolocation sounds by odontocetes (toothed whales). However, lower frequency man-made noises are more likely to affect detection of communication calls and other potentially important natural sounds such as surf and prey noise. It may also affect communication signals when they occur near the noise band and thus reduce the communication space of animals (e.g., Clark *et al.* 2009) and cause increased stress levels (e.g., Foote *et al.* 2004; Holt *et al.* 2009).

Unlike TS, masking can potentially impact the species at population, community, or even ecosystem levels, as well as individual levels. Masking affects both senders and receivers of the signals and could have long-term chronic effects on marine mammal species and populations. Recent science suggests that low frequency ambient sound levels have increased by as much as 20 dB (more than 3 times in terms of SPL) in the world's ocean from pre-industrial periods, and most of these increases are from distant shipping (Hildebrand 2009). All anthropogenic noise sources, such as those from vessels traffic, pile driving, dredging, and dismantling existing bridge by mechanic means, contribute to the elevated ambient noise levels, thus intensify masking.

Nevertheless, the sum of noise from the proposed WSDOT construction activities is confined in an area that is bounded by landmass, therefore, the noise generated is not expected to contribute to increased ocean ambient noise. Due to shallow water depth near the ferry terminals, underwater sound propagation for low-frequency sound (which is the major noise source from pile driving) is expected to be poor.

Finally, exposure of marine mammals to certain sounds could lead to behavioral disturbance (Richardson *et al.* 1995), such as: Changing durations of surfacing and dives, number of blows per surfacing, or moving direction and/or speed; reduced/increased vocal activities, changing/cessation of certain behavioral activities (such as socializing or feeding); visible startle response or aggressive behavior (such as tail/fluke slapping or jaw clapping), avoidance of areas where noise sources are located, and/or flight responses (e.g., pinnipeds flushing into water from haulouts or rookeries).

The biological significance of many of these behavioral disturbances is difficult to predict, especially if the detected disturbances appear minor. However, the consequences of behavioral modification could be expected to be biologically significant if the change affects growth, survival, and reproduction. Some of these significant behavioral modifications include:

- Drastic change in diving/surfacing patterns (such as those thought to be causing beaked whale stranding due to exposure to military mid-frequency tactical sonar);
- Habitat abandonment due to loss of desirable acoustic environment; and
- Cease feeding or social interaction.

For example, at the Guerreo Negro Lagoon in Baja California, Mexico, which is one of the important breeding grounds for Pacific gray whales, shipping and dredging associated with a salt works may have induced gray whales to abandon the area through most of the 1960s (Bryant *et al.* 1984). After these activities stopped, the lagoon was reoccupied, first by single whales and later by cow-calf pairs.

The onset of behavioral disturbance from anthropogenic noise depends on both external factors (characteristics of noise sources and their paths) and the receiving animals (hearing, motivation, experience, demography) and is also difficult to predict (Southall *et al.* 2007).

The proposed project area is not believed to be a prime habitat for marine mammals, nor is it considered an area

frequented by marine mammals. Therefore, behavioral disturbances that could result from anthropogenic noise associated with SF–OBB construction activities are expected to affect only a small number of marine mammals on an infrequent basis.

Currently NMFS uses 160 dB re 1 µPa (rms) at received level for impulse noises (such as impact pile driving, mechanic splitting and pulverizing) as the onset of marine mammal behavioral harassment, and 120 dB re 1 µPa (rms) for non-impulse noises (vibratory pile driving, saw cutting, drilling, and dredging). For the WSDOT's proposed Orcas Island and Friday Harbor ferry terminal dolphin replacement construction projects, only the 120 dB re 1 µPa (rms) threshold is considered because only vibratory pile removal and pile driving would be used.

As far as airborne noise is concerned, the estimated in-air source level from vibratory pile driving a 30-in steel pile is estimated at 97.8 dB re 1 µPa at 15 m (50 feet) from the pile (Laughlin 2010b). Using the spreading loss of 6 dB per doubling of distance, it is estimated that the distances to the 90 dB and 100 dB thresholds were estimated at 37 m and 12 m, respectively. The nearest pinniped haulout is 1 km away south of the Orcas Island terminal and 4 km northeast of the Friday Harbor ferry terminal offshore of Shaw Island.

Potential Effects on Marine Mammal Habitat

The primary potential impacts to marine mammals habitat are associated with elevated sound levels produced by vibratory pile removal and pile driving in the area. However, other potential impacts to the surrounding habitat from physical disturbance are also possible.

Potential Impacts on Prey Species

With regard to fish as a prey source for cetaceans and pinnipeds, fish are known to hear and react to sounds and to use sound to communicate (Tavolga *et al.* 1981) and possibly avoid predators (Wilson and Dill 2002). Experiments have shown that fish can sense both the strength and direction of sound (Hawkins 1981). Primary factors determining whether a fish can sense a sound signal, and potentially react to it, are the frequency of the signal and the strength of the signal in relation to the natural background noise level.

The level of sound at which a fish will react or alter its behavior is usually well above the detection level. Fish have been found to react to sounds when the sound level increased to about 20 dB above the detection level of 120 dB (Ona 1988); however, the response threshold can depend on the time of year and the fish's physiological condition (Engas *et al.* 1993). In general, fish react more strongly to pulses of sound rather than non-pulse signals (such as noise from vessels) (Blaxter *et al.* 1981), and a quicker alarm response is elicited when the sound signal intensity rises rapidly compared to sound rising more slowly to the same level.

Further, during the coastal construction only a small fraction of the available habitat would be ensonified at any given time. Disturbance to fish species would be short-term and fish would return to their pre-disturbance behavior once the pile driving activity ceases. Thus, the proposed construction would have little, if any, impact on the abilities of marine mammals to feed in the area where construction work is planned.

Finally, the time of the proposed construction activity would avoid the spawning season of the ESA-listed salmonid species.

Water and Sediment Quality

Short-term turbidity is a water quality effect of most in-water work, including removing and installing piles. WSF will comply with state water quality standards during these operations by limiting the extent of turbidity to the immediate project area.

Roni and Weitkamp (1996) monitored water quality parameters during a pier replacement project in Manchester, Washington. The study measured water quality before, during, and after pile removal and pile replacement. The study found that construction activity at the site had ''little or no effect on dissolved oxygen, water temperature, and salinity'', and turbidity (measured in nephelometric turbidity units [NTU]) at all depths nearest the construction activity was typically less than 1 NTU higher than stations farther from the construction area throughout construction. Similar results were recorded during pile removal operations at two WSF ferry facilities. At the Friday Harbor terminal, localized turbidity levels (from three timber pile removal events) were generally less than 0.5 NTU higher than background levels and never exceeded 1 NTU. At the Eagle Harbor maintenance facility, local turbidity levels (from removal of timber and steel piles) did not exceed 0.2 NTU above background levels. In September 2004, water quality monitoring conducted at the Friday Harbor Ferry Terminal during three pile-removal events showed turbidity levels did not exceed 1 NTU over background conditions and were generally less than 0.5 NTU over background levels. In general, turbidity associated with pile installation is localized to about a 25-foot radius around the pile (Everitt *et al.* 1980).

Cetaceans are not expected to be close enough to the Orcas Island and Friday Harbor ferry terminals to experience turbidity, and any pinnipeds will be transiting the terminal areas and could avoid the localized areas of turbidity. Therefore, the impact from increased turbidity levels is expected to be discountable to marine mammals. Removal of the timber dolphins at Orcas Island and Friday Harbor ferry terminal will result in 197 creosote-treated piles (334 tons) removed from the marine environment. This will result in the potential, temporary and localized sediment re-suspension of some of the contaminants associated with creosote, such as polycyclic aromatic hydrocarbons. However, the actual removal of the creosote-treated wood piles from the marine environment will result in a long-term improvement in water and sediment quality, meeting the goals of WSF's Creosote Removal Initiative started in 2000. The net impact is a benefit to marine organisms, especially toothed whales and pinnipeds that are high in the food chain and bioaccumulate these toxins. This is especially a concern for long-lived species that spend their entire life in Puget Sound, such as Southern Resident killer whales (NMFS 2008a).

Passage Obstructions

Pile removal and installation operations at the Orcas Island and Friday Harbor ferry terminals will not obstruct movements of marine mammals. The operations at Orcas Island will occur within 75 m of the shoreline leaving 1 km of the channel for marine mammals to pass. At Friday Harbor, operations will occur within 160 m of the shoreline leaving 0.4 km of the harbor for marine mammals to pass. Further, a construction barge will be used to remove and install the pilings.

Potential Impacts on Availability of Affected Species or Stock for Taking for Subsistence Uses

No subsistence harvest of marine mammals occur in the proposed action area.

Proposed Mitigation Measures

In order to issue an incidental take authorization under Section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable adverse

impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses.

For the proposed Orcas Island and Friday Harbor ferry terminals dolphin replacement construction work, WSDOT proposed the following mitigation measures to minimize the potential impacts to marine mammals in the project vicinity. These mitigation measures would be employed during all pile removal and installation activities at the Orcas Island and Friday Harbor ferry terminals. The language in monitoring measures would be included in the Contract Plans and Specifications and must be agreed upon by the contractor prior to any pile activities.

Since the measured source levels (at 10 and 16 m) of the vibratory hammer involved in pile removal and pile driving are below NMFS current thresholds for Level A takes, i.e., below 180 dB re 1 μPa (rms), no exclusion zone would be established, and there would be no required power-down and shutdown measures. Instead, WSDOT would establish and monitor the 120 dB re 1 μPa (rms) zone of influence (ZOI, see below Proposed Monitoring and Reporting section).

One major mitigation measure for WSDOT's proposed pile removal and pile driving activities is ramping up, or soft start, of vibratory pile hammers. The purpose of this procedure is to reduce the startling behavior of marine mammals in the vicinity of the proposed construction activity from sudden loud noise.

Soft start requires contractors to initiate the vibratory hammer at reduced power for 15 seconds with a 1 minute interval, and repeat such procedures for an additional two times.

In addition, monitoring for marine mammal presence will take place 20 minutes before, during and 30 minutes after pile driving to ensure that marine mammals are not injured by the proposed construction activities (see Proposed Monitoring and Reporting section below).

Finally, if the number of any allotted marine mammal takes (see *Estimated Take by Incidental Harassment* section below) reaches the limit under the IHA (if issued), WSDOT will implement shutdown and power down measures if such species/stock of animal approaches the 120 dB Level B harassment zone.

Proposed Monitoring and Reporting

In order to issue an ITA for an activity, Section 101(a)(5)(D) of the MMPA states that NMFS must set forth ''requirements pertaining to the monitoring and reporting of such taking''. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for ITAs must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area.

Proposed Monitoring Measures

The monitoring plan proposed by WSDOT can be found in its IHA application. The plan may be modified or supplemented based on comments or new information received from the public during the public comment period. A summary of the primary components of the plan follows.

(1) Protected Species Observers (PSOs)

WSDOT will employ qualified protected species observers (PSOs) to monitor the 120 dB re 1 μPa (rms) for marine mammals. Qualifications for marine mammal observers include:

- Visual acuity in both eyes (correction is permissible) sufficient for discernment of moving targets at the water's surface with ability to estimate target size and distance. Use of binoculars may be necessary to correctly identify the target.
- Advanced education in biological science, wildlife management, mammalogy or related fields (Bachelors degree or higher is preferred), but not required.
- Experience or training in the field identification of marine mammals (cetaceans and pinnipeds).
- Sufficient training, orientation or experience with the construction operation to provide for personal safety during observations.
- Ability to communicate orally, by radio or in person, with project personnel to provide real time information on marine mammals observed in the area as necessary.
- Experience and ability to conduct field observations and collect data according to assigned protocols (this may include academic experience).
- Writing skills sufficient to prepare a report of observations that would include such information as the number and type of marine mammals observed; the behavior of marine mammals in the project area during construction, dates and times when observations were conducted; dates and times when in-water construction activities were conducted; and dates and times when marine mammals were present at or within the defined ZOI.

(2) Monitoring Protocols

PSOs will be present on site at all times during pile removal and driving. Marine mammal behavior, overall numbers of individuals observed, frequency of observation, and the time corresponding to the daily tidal cycle will be recorded.

WSF proposes the following methodology to estimate marine mammals that were taken as a result of the proposed Orcas Island and Friday Harbor ferry terminal construction work:

- A range finder or hand-held global positioning system device will be used to ensure that the 120 dB re 1 μPa (rms) Level B behavioral harassment ZOI is monitored.
- A 20-minute pre-construction marine mammal monitoring will be required before the first pile driving or pile removal of the day. A 30-minute post-construction marine mammal monitoring will be required after the last pile driving or pile removal of the day. If the constructors take a break between subsequent pile driving or pile removal for more than 30 minutes, then additional pre-construction marine mammal monitoring will be required before the next start-up of pile driving or pile removal.
- If marine mammals are observed, the following information will be document:
  - Species of observed marine mammals;
  - Number of observed marine mammal individuals;
  - Behavioral of observed marine mammals;
  - Location within the ZOI; and
  - Animals' reaction (if any) to pile-driving activities.
- During vibratory pile removal and driving, one land-based biologist will monitor the area from the terminal work site, and one boat with a qualified PSO shall navigate the ZOI in a circular path.
- In addition, WSDOT will contact the Orca Network and/or Center for Whale Research to find out the location of the nearest marine mammal sightings. Sightings are called or emailed into the Orca Network and immediately distributed to other sighting networks including: The Northwest Fisheries Science Center of NOAA Fisheries, the Center for Whale Research, Cascadia Research, the Whale Museum Hotline, and the British Columbia Sightings Network.
- Marine mammal occurrence information collected by the Orca Network also includes detection by the

following hydrophone systems: (1) The SeaSound Remote Sensing Network, a system of interconnected hydrophones installed in the marine environment of Haro Strait (west side of San Juan Island) to study killer whale communication, underwater noise, bottomfish ecology, and local climatic conditions, and (2) A hydrophone at the Port Townsend Marine Science Center that measures average underwater sound levels and automatically detects unusual sounds.

NMFS has reviewed the WSDOT's proposed marine mammal monitoring protocol, and has determined the applicant's monitoring program is adequate, particularly as it relates to assessing the level of taking or impacts to affected species. The land-based PSO is expected to be positioned in a location that will maximize his/her ability to detect marine mammals and will also utilize binoculars to improve detection rates. In addition, the boat-based PSO will cruise within the 120 dB ZOI, which is not a particularly large zone, thereby allowing him/her to conduct additional monitoring with binoculars. With respect to WSDOT's take limits, NMFS is primarily concerned that WSDOT could reach its Southern Resident killer whale limit. However, killer whales have large dorsal fins and can be easily spotted from great distances. Further, Southern Resident killer whales typically move in groups which makes visual detection much easier. In addition, added underwater acoustic monitoring by Orca Network in the region would further provide additional detection, since resident killer whales are very vocal.

Proposed Reporting Measures

WSF will provide NMFS with a draft monitoring report within 90 days of the conclusion of the proposed construction work. This report will detail the monitoring protocol, summarize the data recorded during monitoring, and estimate the number of marine mammals that may have been harassed.

If comments are received from the NMFS Northwest Regional Administrator or NMFS Office of Protected Resources on the draft report, a final report will be submitted to NMFS within 30 days thereafter. If no comments are received from NMFS, the draft report will be considered to be the final report.

Estimated Take by Incidental Harassment

As mentioned earlier in this document, a worst-case scenario for the Orcas Island ferry terminal project assumes that it may take 3 days to remove the existing piles and 2 days to install the new piles. The maximum total number of hours of pile removal activity is about 17.2 hours, and pile-driving activity is about 2.3 hours (averaging about 3.9 hours of active pile removal/driving for each construction day).

A worst-case scenario for the Friday Harbor ferry terminal project assumes that it may take 5 days to remove the existing piles and 5 days to install the new piles. The maximum total number of hours of pile removal activity is about 34.75 hours, and pile-driving activity is about 4.3 hours (averaging about 3.9 hours of active pile removal/driving for each construction day).

Also, as described earlier, for non-impulse noise, NMFS uses 120 dB re 1 µPa (rms) as the threshold for Level B behavioral harassment. The distance to the 120 dB re 1 µPa (rms) isopleth due to vibratory pile driving for the Orcas Island ferry terminal project extends a maximum of 3.5 km (2.2 miles) before land is intersected. For the Friday Harbor ferry terminal project, land is intersected at a maximum of 4.7 km (2.9 miles). To simplify the establishment of the 120 dB re 1 µPa (rms) zone of influence (ZOI) for monitoring, vibratory timber pile removal will conservatively be assumed to extend the same distances as vibratory pile driving. Both of these areas will be monitored during construction to estimate actual harassment take of marine mammals (see below).

Airborne noises can affect pinnipeds, especially resting seals hauled out on rocks or sand spits. The airborne 90 dB re 20 µPa Level B threshold for hauled out harbor seals was estimated at 37 m, and the airborne 100 dB Level B re 10 µPa threshold for all other pinnipeds is estimated at 12 m. This is much closer than the distance to the nearest harbor seal haulout site for the Orcas Island ferry terminal (1 km) and Friday Harbor ferry terminal (4 km).

Incidental take is estimated for each species by estimating the likelihood of a marine mammal being present within a ZOI during active pile driving and removal. Expected marine mammal presence is determined by past observations and general abundance near the Orcas Island and Friday Harbor ferry terminals during the construction window. Typically, potential take is estimated by multiplying the number of animals likely to be present in the action area by the estimated number of days pile removal and pile driving would be conducted. Since there are no density estimates for any Puget Sound population of marine mammal, numbers of marine mammal presence are estimated using local marine mammal data sets (e.g., Orca Network, state and federal agencies), opinions from state and federal agencies, incidental observations from WSF biologists, and the duration for the proposed vibratory pile removal and pile driving activities. Based on the estimates, approximately 150 Pacific harbor seals, 25 California sea lions, 15 northern elephant seals, 25 Steller sea lions, 50 harbor porpoises, 15 Dall's porpoises, 15 Pacific white-sided dolphins, 32 killer whales (24 transient, 8 Southern Resident killer whales), 4 gray whales, 4 humpback whales, and 10 minke whales could be exposed to received noise levels above 120 dB re 1 µPa (rms) from the proposed dolphin replacement work at the Orcas Island ferry terminal. In addition, approximately 200 Pacific harbor seals, 50 California sea lions, 30 northern elephant seals, 50 Steller sea lions, 100 harbor porpoises, 30 Dall's porpoises, 30 Pacific white-sided dolphins, 32 killer whales (24 transient, 8 Southern Resident killer whales), 4 gray whales, 4 humpback whales, and 10 minke whales could be exposure to received noise levels above 120 dB re 1 µPa (rms) from the proposed dolphin replacement work at the Friday Harbor ferry terminal. A summary of the estimated takes is presented in Table 2.

TABLE 2—ESTIMATED NUMBERS OF MARINE MAMMALS THAT MAY BE EXPOSED TO RECEIVED PILE DRIVING AND PILE REMOVAL LEVELS ABOVE 120 dB re 1 µPa (rms)

Species	Orcas Island ferry terminal	Friday Harbor ferry terminal	Total
Pacific harbor seal	150	200	350
California sea lion	25	50	75
Northern elephant seal	15	30	45
Steller sea lion	25	50	75
Harbor porpoise	50	100	150

TABLE 2—ESTIMATED NUMBERS OF MARINE MAMMALS THAT MAY BE EXPOSED TO RECEIVED PILE DRIVING AND PILE REMOVAL LEVELS ABOVE 120 dB re 1 μPa (rms)—Continued

Species	Orcas Island ferry terminal	Friday Harbor ferry terminal	Total
Dall's porpoise	15	30	45
Pacific white-sided dolphin	15	30	45
Killer whale, transient	24	24	48
Killer whale, Southern Resident	8	8	16
Gray whale	4	4	8
Humpback whale	4	4	8
Minke whale	10	10	20

The requested takes represent 2.4% of the Inland Washington stock harbor seals (estimated at 14,612), 0.03% of the U.S. stock California sea lion (estimated at 238,000), 0.04% of the California stock northern elephant seal (estimated at 124,000), 0.15% of the eastern stock Steller sea lion (estimated at 48,519), 1.4% of the Washington Inland waters stock harbor porpoise (estimated at 10,682), 0.08% of the California, Oregon, and Washington stock Dall's porpoise (estimated at 57,549), 0.18% of the California, Oregon, and Washington stock Pacific white-sided dolphin (estimated at 25,233), 13.6% of the West Coast transient killer whale (estimated at 354), 19.0% of Southern Resident killer whale (estimated at 84), 0.02% of the Eastern North Pacific stock gray whale (estimated at 26,000), 0.7% of the Eastern North Pacific stock humpback whale (estimated at 1,100), and 4% of the California/Oregon/Washington stock minke whale (estimated at 500).

Negligible Impact and Small Numbers Analysis and Preliminary Determination

Pursuant to NMFS' regulations implementing the MMPA, an applicant is required to estimate the number of animals that will be ''taken'' by the specified activities (i.e., takes by harassment only, or takes by harassment, injury, and/or death). This estimate informs the analysis that NMFS must perform to determine whether the take resulting from the activity will have a ''negligible impact'' on the species or stock. Level B (behavioral) harassment occurs at the level of the individual(s) and does not assume any resulting population-level consequences, though there are known avenues through which behavioral disturbance of individuals can result in population-level effects. A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (i.e., population-level effects). An estimate of the number of Level B harassment takes alone is not enough information on which to base an impact determination.

In addition to considering estimates of the number of marine mammals that might be ''taken'' through behavioral harassment, NMFS considers other factors, such as the likely nature of any responses (their intensity, duration, etc.), the context of any responses (critical reproductive time or location, migration, etc.), as well as the number and nature of estimated Level A takes, the number of estimated mortalities, and effects on habitat.

The WSDOT's proposed Orcas Island and Friday Harbor ferry terminal construction projects would conduct vibratory pile removal and pile driving to replace dolphin structures. Elevated underwater noises are expected to be generated as a result of pile removal and pile driving activities. However, noise levels from the machinery and activities are not expected to reach to the level that may cause TTS, injury (PTS included), or mortality to marine mammals. Therefore, NMFS does not expect that any animals would experience Level A (including injury) harassment or Level B harassment in the form of TTS from being exposed to in-water pile driving and pile removal associated with WSDOT construction project.

Based on long-term marine mammal monitoring and studies in the vicinity of the proposed construction areas, it is estimated that approximately 350 Pacific harbor seals, 75 California sea lions, 45 northern elephant seals, 75 Steller sea lions, 150 harbor porpoises, 45 Dall's porpoises, 45 Pacific white-sided dolphins, 64 killer whales, 8 gray whales, 8 humpback whales, and 20 minke whales could be exposed to received noise levels above 120 dB re 1 μPa (rms) from the proposed construction work at Orcas Island and Friday Harbor ferry terminals. These numbers represent approximately 0.03%—19.0% of the stocks and populations of these species could be affected by Level B behavioral harassment. As mentioned earlier in this document, the worst case scenario for the proposed construction work would only take a total of 5 days at Orcas Island ferry terminal and 10 days at the Friday Harbor ferry terminal.

In addition, these low intensity, localized, and short-term noise exposures (i.e., 120 dB re 1 μPa (rms) from vibratory pile removal and pile driving for a total of 15 days) are expected to cause brief startle reactions or short-term behavioral modification by the animals. These brief reactions and behavioral changes are expected to disappear when the exposures cease. In addition, no important feeding and/or reproductive areas of marine mammals is known to be near the proposed action area. Therefore, these levels of received underwater construction noise from the proposed Orcas Island and Friday Harbor ferry terminal construction projects are not expected to affect marine mammal annual rates of recruitment or survival. The maximum estimated 120 dB maximum isopleths from vibratory pile driving is approximately 3.5 km at Orcas Island and 4.7 km at Friday Harbor from the pile before being blocked by landmass, respectively.

The nearest known haulout site to the Orcas Island ferry terminal is 1 km away south of the terminal offshore of Shaw Island, and 4 km northeast of the Friday Harbor ferry terminal offshore of Shaw Island. However, it is estimated that airborne noise from pile driving and removal would fall below 90 dB and 100 dB re 1 20 μPa at 37 m and 12 m from the pile, respectively. Therefore, pinnipeds hauled out on Shaw Island will not be affected.

For the reasons discussed in this document, NMFS has preliminarily determined that the impact of vibratory pile removal and pile driving associated with dolphin replacements at Orcas Island and Friday Harbor ferry terminals would result, at worst, in the Level B harassment of small numbers of 11 marine mammals that inhabit or visit the area. While behavioral modifications, including temporarily vacating the area around the construction site, may be made by these

species to avoid the resultant visual and acoustic disturbance, the availability of alternate areas within Washington coastal waters and haul-out sites has led NMFS to preliminarily determine that this action will have a negligible impact on these species in the vicinity of the proposed construction area.

In addition, no take by TTS, Level A harassment (injury) or death is anticipated and harassment takes should be at the lowest level practicable due to incorporation of the mitigation and monitoring measures mentioned previously in this document.

Proposed Incidental Harassment Authorization

This section contains a draft of the IHA itself. The wording contained in this section is proposed for inclusion in the IHA (if issued).

1. This Authorization is valid from May 1, 2013, through February 15, 2014.

2. This Authorization is valid only for activities associated in-water construction work at Orcas Island and Friday Harbor ferry terminals in the State of Washington.

3.(a) The species authorized for incidental harassment takings, Level B harassment only, are: Pacific harbor seal (*Phoca vitulina richardsi*), California sea lion (*Zalophus californianus*), northern elephant seal (*Mirounga angustirostris*), Steller sea lion (*Eumetopias jubatus*), harbor porpoise (*Phocoena phocoena*), Dall's porpoise (*Phocoenoides dalli*), Pacific white-sided dolphin (*Lagenorhynchus obliquidens*), killer whale (*Orcinus orca*), gray whale (*Eschrichtius robustus*), humpback whale (*Megaptera novaeangliae*), and minke whale (*Balaenoptera acutorostra*).

(b) The authorization for taking by harassment is limited to the following acoustic sources and from the following activities:

(i) Vibratory pile removal; and

(ii) Vibratory pile driving.

(c) The taking of any marine mammal in a manner prohibited under this Authorization must be reported within 24 hours of the taking to the Northwest Regional Administrator (206–526–6150), National Marine Fisheries Service (NMFS) and the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, at (301) 427–8401, or his designee (301–427–8418).

4. The holder of this Authorization must notify the Chief of the Permits and Conservation Division, Office of Protected Resources, at least 48 hours prior to the start of activities identified in 3(b) (unless constrained by the date of issuance of this Authorization in which case notification shall be made as soon as possible).

5. Prohibitions:

(a) The taking, by incidental harassment only, is limited to the species listed under condition 3(a) above and by the numbers listed in Table 2. The taking by Level A harassment, injury or death of these species or the taking by harassment, injury or death of any other species of marine mammal is prohibited and may result in the modification, suspension, or revocation of this Authorization.

(b) The taking of any marine mammal is prohibited whenever the required protected species observers (PSOs), required by condition 7(a), are not present in conformance with condition 7(a) of this Authorization.

6. Mitigation:

(a) Ramp Up (Soft Start):

Vibratory hammer for pile removal and pile driving shall be initiated at reduced power for 15 seconds with a 1 minute interval, and be repeated with this procedure for an additional two times.

(b) Marine Mammal Monitoring:

Monitoring for marine mammal presence shall take place 20 minutes before, during and 30 minutes after pile driving to ensure that marine mammals are not injured by the construction activities.

(c) Power Down and Shutdown Measures:

If the number of any allotted marine mammal takes reaches the limit under the IHA (if issued), WSDOT shall implement shutdown and power down measures if such species/stock of animal approaches the Level B harassment zone.

7. Monitoring:

(a) Protected Species Observers: WSDOT shall employ qualified protected species observers (PSOs) to monitor the 120 dB re 1 μPa (rms) zone of influence (ZOI) for marine mammals. Qualifications for marine mammal observers include:

(i) Visual acuity in both eyes (correction is permissible) sufficient for discernment of moving targets at the water's surface with ability to estimate target size and distance. Use of binoculars may be necessary to correctly identify the target.

(ii) Advanced education in biological science, wildlife management, mammalogy or related fields (bachelors degree or higher is preferred), but not required.

(iii) Experience or training in the field identification of marine mammals (cetaceans and pinnipeds).

(iv) Sufficient training, orientation or experience with the construction operation to provide for personal safety during observations.

(v) Ability to communicate orally, by radio or in person, with project personnel to provide real time information on marine mammals observed in the area as necessary.

(vi) Experience and ability to conduct field observations and collect data according to assigned protocols (this may include academic experience).

(vii) Writing skills sufficient to prepare a report of observations that would include such information as the number and type of marine mammals observed; the behavior of marine mammals in the project area during construction, dates and times when observations were conducted; dates and times when in-water construction activities were conducted; and dates and times when marine mammals were present at or within the defined ZOI.

(b) Monitoring Protocols: PSOs shall be present on site at all times during pile removal and driving.

(i) A range finder or hand-held global positioning system device will be used to ensure that the 120 dB re 1 μPa (rms) Level B behavioral harassment ZOI is monitored.

(ii) A 20-minute pre-construction marine mammal monitoring will be required before the first pile driving or pile removal of the day. A 30-minute post-construction marine mammal monitoring will be required after the last pile driving or pile removal of the day. If the constructors take a break between subsequent pile driving or pile removal for more than 30 minutes, then additional pre-construction marine mammal monitoring will be required before the next start-up of pile driving or pile removal.

(iii) If marine mammals are observed, the following information will be document:

(A) Species of observed marine mammals;

(B) Number of observed marine mammal individuals;

(C) Behavioral of observed marine mammals;

(D) Location within the ZOI; and

(E) Animals' reaction (if any) to pile-driving activities

(iv) During vibratory pile removal and driving, one land-based biologist will monitor the area from the terminal work site, and one boat with a qualified PSO shall navigate the ZOI in a circular path.

(v) WSDOT shall contact the Orca Network and/or Center for Whale Research to find out the location of the nearest marine mammal sightings.

(vi) WSDOT shall also utilize marine mammal occurrence information collected by the Orca Network using

hydrophone systems to maximize marine mammal detection in the project vicinity.

8. Reporting:

(a) WSF shall provide NMFS with a draft monitoring report within 90 days of the conclusion of the construction work. This report shall detail the monitoring protocol, summarize the data recorded during monitoring, and estimate the number of marine mammals that may have been harassed.

(b) If comments are received from the NMFS Northwest Regional Administrator or NMFS Office of Protected Resources on the draft report, a final report shall be submitted to NMFS within 30 days thereafter. If no comments are received from NMFS, the draft report will be considered to be the final report.

9. This Authorization may be modified, suspended or withdrawn if the holder fails to abide by the conditions prescribed herein or if the authorized taking is having more than a negligible impact on the species or stock of affected marine mammals, or if there is an unmitigable adverse impact on the availability of such species or stocks for subsistence uses.

10. A copy of this Authorization and the Incidental Take Statement must be in the possession of each contractor who performs the construction work at Orcas Island and Friday Harbor ferry terminals.

11. WSDOT is required to comply with the Terms and Conditions of the Incidental Take Statement corresponding to NMFS' Biological Opinion.

National Environmental Policy Act (NEPA)

NMFS is currently preparing an Environmental Assessment, pursuant to NEPA, to determine whether or not this proposed activity may have a significant effect on the human environment. This analysis will be completed prior to the issuance or denial of the IHA.

Endangered Species Act (ESA)

The humpback whale, Southern Resident stock of killer whale, and the eastern population of Steller sea lions, are the only marine mammal species currently listed under the ESA that could occur in the vicinity of WSDOT's proposed construction projects. NMFS' Permits and Conservation Division has initiated consultation with NMFS' Protected Resources Division under section 7 of the ESA on the issuance of an IHA to WSDOT under section 101(a)(5)(D) of the MMPA for this activity. Consultation will be concluded prior to a determination on the issuance of an IHA.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to authorize the take of marine mammals incidental to WSDOT's Orcas Island and Friday Harbor ferry terminal construction projects, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: February 5, 2013.

Helen M Golde,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2013–02864 Filed 2–7–13; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Addition

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Addition to the Procurement List.

SUMMARY: This action adds a service to the Procurement List that will be provided by a nonprofit agency employing persons who are blind or have other severe disabilities.

DATES: *Effective Date:* 3/11/2013.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia, 22202–3259.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Addition

On 11/30/2012 (77 FR 71400–71401), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed addition to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agency to provide the service and impact of the addition on the current or most recent contractor, the Committee has determined that the service listed below is suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organization that will provide the service to the Government.

2. The action will result in authorizing a small entity to provide the service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the service proposed for addition to the Procurement List.

End of Certification

Accordingly, the following service is added to the Procurement List:

Service

Service Type/Locations: Hospital Housekeeping Service, Veterinary Clinic, 533 Solomons Rd, Fort Story, VA. Health/Dental Clinic, Bldg. 649, New Guinea Road, Fort Story, VA. McDonald Army Health Center (MCAHC), 576 Jefferson Ave., Fort Eustis, VA.

NPA: Enterprise Professional Services, Inc., Austin, TX

Contracting Activity: Dept of the Army, W40M USA MEDCOM HCAA, Fort Sam Houston, TX

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2013–02881 Filed 2–7–13; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to and Deletions from the Procurement List.

SUMMARY: The Committee is proposing to add products and services to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities and deletes products previously furnished by such agencies.

DATES: *Comments Must Be Received on or Before:* 3/11/2013.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely

Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia, 22202–3259.

FOR FURTHER INFORMATION OR TO SUBMIT COMMENTS CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the products and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following products and services are proposed for addition to Procurement List for production by the nonprofit agencies listed:

Products

NSN: 7025–00–NIB–0004—Mouse, Optical Sensor, Black and Grey, Ergonomic shaped NPA: L.C. Industries for the Blind, Inc., Durham, NC
Contracting Activity: General Services Administration, New York, Ny Coverage: A-List for the Total Government Requirement as aggregated by the General Services Administration.
NSN: 7510–00–NIB–9843—Self Stick Rectangular Flag, .5″ x 1.7″, Multi Pack (Red/yellow/blue/green)
NPA: Association for the Blind and Visually Impaired—Goodwill Industries of Greater Rochester, Rochester, NY
Contracting Activity: General Services Administration, New York, Ny Coverage: A-List for the Total Government Requirement as aggregated by the General Services Administration.

Services

Service Type/Location: Custodial/Janitorial, Cochiti Lake Project Office, 82 Dam Crest Road, Pena Blanca, NM.
NPA: Adelante Development Center, Inc., Albuquerque, NM
Contracting Activity: Dept of the Army, W075 ENDIST Albuquerque, Albuquerque, NM.
Service Type/Location: Custodial Service, Consumer Financial Protection Bureau, 1625 Eye Street NW., Washington, DC.
NPA: Service Disabled Veterans Business Association, Silver Springs, MD
Contracting Activity: Consumer Financial Protection Bureau, Cfpb Procurement, Washington, DC.
Service Type/Location: Custodial Service, Toulson Courthouse, 129 East Main Street, Salisbury, MD.
NPA: Worcester County Developmental Center, Newark, MD
Contracting Activity: Public Buildings Service, GSA/PBS/R03 South Service Center, Philadelphia, PA.

Deletions

The following products are proposed for deletion from the Procurement List:

Products

NSN: 7045–01–568–9694—USB 2.0 Hard Drive, Portable, 320G
NSN: 7045–01–599–9345—USB Flash Drive, 256-Bit AES Encryption, Level 3 Encrypted, Anti-Virus, 4GB
NSN: 7045–01–599–9346—USB Flash Drive, 256-Bit AES Encryption, Level 3 Encrypted, Anti-Virus, 32GB
NSN: 7045–01–599–9348—USB Flash Drive, 256-Bit AES Encryption, Level 3 Encrypted, Anti-Virus, 8GB
NSN: 7045–01–599–9352—USB Flash Drive, 256-Bit AES Encryption, Level 3 Encrypted, 2GB
NSN: 7045–01–599–9353—USB Flash Drive, 256-Bit AES Encryption, Level 3 Encrypted, Anti-Virus, 16GB
NSN: 7045–01–599–9354—USB Flash Drive, 256-Bit AES Encryption, Level 3 Encrypted, Anti-Virus, 2GB
NPA: North Central Sight Services, Inc., Williamsport, PA
Contracting Activity: General Services Administration, New York, NY
NSN: 7420–01–484–1758—Clipboard w/ Calculator
NPA: MidWest Enterprises for the Blind, Inc., Kalamazoo, MI
Contracting Activity: General Services Administration, New York, NY

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2013–02880 Filed 2–7–13; 8:45 am]

BILLING CODE 6353–01–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting Notice

TIME AND DATE: Wednesday, February 13, 2013, 10:00 a.m.—11:00 a.m.

PLACE: Room 420, Bethesda Towers, 4330 East West Highway, Bethesda, Maryland.

STATUS: Commission Meeting—Open to the Public.

Matters To Be Considered

Decisional Matter: Sections 1112/1118 Requirements for Third Party Conformity Assessment Bodies—Draft Final.

A live webcast of the Meeting can be viewed at *www.cpsc.gov/webcast.*

For a recorded message containing the latest agenda information, call (301) 504–7948.

CONTACT PERSON FOR MORE INFORMATION: Todd A. Stevenson, Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, (301) 504–7923.

Dated: February 5, 2013.

Todd A. Stevenson,

Secretary.

[FR Doc. 2013–02969 Filed 2–6–13; 11:15 am]

BILLING CODE 6355–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9779–6]

Notice of Availability for Public Review and Comment: Draft EPA Climate Change Adaptation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Scientific evidence demonstrates that the climate is changing at an increasingly rapid rate, outside the range to which society has adapted in the past. Climate change can pose significant challenges to the EPA's ability to fulfill its mission. The U.S. Environmental Protection Agency is committed to identifying and responding to the challenges that a changing climate poses to human health and the environment. It is essential; therefore, that the EPA adapt to climate change in order to continue fulfilling its statutory, regulatory and programmatic requirements, chief among these protection of human health and the environment. Adaptation will involve anticipating and planning for changes in climate and incorporating considerations of climate change into many of the Agency's programs, policies, rules and operations to ensure they are effective under changing climatic conditions. Adaptation also necessitates close coordination between EPA and its many partners and stakeholders.

EPA and other Federal Agencies and Departments have developed draft Agency Climate Change Adaptation Plans in response to the President's October 2009 Executive Order (E.O. 13514—*''Federal Leadership in Environmental, Energy, and Economic Performance''*) and the March, 2011 *Implementing Instructions to all Federal Department and Agencies.* Today, EPA announces the availability of a public review draft of its Agency *Plan.* The draft *Plan* will be available for a 60-day public review.

DATES: The public should respond to the EPA with comment via the public docket no later than April 9, 2013. Only

comments received by the deadline can be considered by the Agency in finalizing its plan.

ADDRESSES: If you have questions about responding to this notice, please contact Catherine Allen by phone (202–566–1039), or by mail (1200 Pennsylvania Ave. NW., Washington, DC 20460).

The public review draft of EPA's *Climate Change Adaptation Plan* has been posted to a public docket and is available on the Agency docket Web site at this URL address: *http://www.epa.gov/dockets/index.htm.* It is Docket Number EPA–HQ–OA–2012–0247.

SUPPLEMENTARY INFORMATION: EPA is working to fulfill its mission to protect human health and the environment. Many of the goals EPA is working to attain (*e.g.,* clean air, safe drinking water) are sensitive to changes in weather and climate. Until now, EPA has been able to assume that climate is relatively stable and future climate would mirror past climate. However, with climate changing at an increasingly rapid rate and outside the range to which society has adapted in the past, climate change is posing new challenges to EPA's ability to fulfill its mission.

This Plan will help guide the Agency to prepare for future changes in climate and to incorporate considerations of climate change into its mission-driven activities. Climate adaptation planning will help EPA continue to fulfill its mission of protecting human health and the environment even as the climate changes.

EPA considers public input to be essential for the development of this *Plan.* This input will also help the Agency strengthen its partnerships with states, tribes, local communities, and non-governmental organizations—many of which have already begun to develop and implement adaptation measures.

Dated: January 24, 2013.

Michael Goo,

Associate Administrator, Office of Policy.

[FR Doc. 2013–02918 Filed 2–7–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9007–5]

Environmental Impacts Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/compliance/nepa/.*

Weekly receipt of Environmental Impact Statements Filed 01/28/2013 Through 02/01/2013

Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *http://www.epa.gov/compliance/nepa/eisdata.html.*

SUPPLEMENTARY INFORMATION: As of October 1, 2012, EPA will not accept paper copies or CDs of EISs for filing purposes; all submissions on or after October 1, 2012 must be made through e-NEPA.

While this system eliminates the need to submit paper or CD copies to EPA to meet filing requirements, electronic submission does not change requirements for distribution of EISs for public review and comment. To begin using e-NEPA, you must first register with EPA's electronic reporting site—*https://cdx.epa.gov/epa_home.asp.*

EIS No. 20130019, Draft EIS, USFS, OR, Ochoco Summit Trail System Project, Ochoco National Forest, Wheeler and Crook Counties, OR, Comment Period Ends: 03/25/2013, Contact: Dede Steele 541–416–6500.

EIS No. 20130020, Second Final EIS (Tiering), FHWA, ME, Aroostook County Transportation Study, Tier 2—Presque Isle Bypass, Aroostook County, ME, Review Period Ends: 03/11/2013, Contact: Mark Hasselmann 207–512–4913.

EIS No. 20130021, Draft EIS, USFS, MS, Revised Land and Resource Management Plan for the National Forests in Mississippi, Comment Period Ends: 05/08/2013, Contact: Jeff Long 601–965–1629.

EIS No. 20130022, Final EIS, NPS, AK, Brooks River Visitor Access, Katmai National Park and Preserve, AK, Review Period Ends: 03/11/2013, Contact: Brooke Merrell (907) 644–3397.

EIS No. 20130023, Final EIS, BR, CA, Water Transfer Program for the San Joaquin River Exchange Contractors Water Authority, 2014–2038, To Execute Agreements for Water Transfers/or Exchanges, San Joaquin Valley, Fresno, Madera, Merced, and Stanislaus Counties, CA, Review Period Ends: 03/11/2013, Contact: Brad Hubbard 916–978–5204.

EIS No. 20130024, Draft EIS, USFS, MT, Pilgrim Creek Timber Sale Project, Kootenai National Forest, Cabinet Ranger District, Sanders County, MT, Comment Period Ends: 03/25/2013, Contact: Doug Grupenhoff 406–827–0741.

EIS No. 20130025, Draft EIS, CALTRAN, CA, State Route 79 Realignment Project, Domenigoni Parkway to Gilman Springs Road, Riverside County, CA, Comment Period Ends: 03/25/2013, Contact: Aaron Burton 909–383–2841.

Amended Notices

EIS No. 20120401, Final EIS, DOE, MA, Adoption—Cape Wind Energy Project Nantucket Sound, Offshore of Massachusetts, DOE/EIS–0470, Barnstable, Nantucket and Duke Counties, MA and Washington County, RI, Review Period Ends: 03/11/2013, Contact: Matthew McMillen 202–586–7248.

Revision to FR Notice Published 12/31/2012; Extending Review Period from 01/29/2013 to 03/11/2013.

Dated: February 5, 2013.

Cliff Rader,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2013–02916 Filed 2–7–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9777–1]

Clean Air Act Advisory Committee (CAAAC): Notice of Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of meeting.

SUMMARY: The Environmental Protection Agency (EPA) established the Clean Air Act Advisory Committee (CAAAC) on November 19, 1990, to provide independent advice and counsel to EPA on policy issues associated with implementation of the Clean Air Act of 1990. The Committee advises on economic, environmental, technical, scientific and enforcement policy issues.

DATES: *Dates & Addresses:* Open meeting notice; Pursuant to 5 U.S.C. App. 2 Section 10(a) (2), notice is hereby given that the Clean Air Act Advisory Committee will hold its next open meeting on February 27, 2013 from 8:30 a.m. to 4:00 p.m. at the Crowne Plaza Old Town Alexandria located at 901 North Fairfax Street, Alexandria, VA 22314. Seating will be available on a first come, first served basis. The Permits, New Source Review and Toxics Subcommittee will meet at the same location on February 26, 2013 from 1:30 a.m. to 3:30 p.m. The agenda for the

CAAAC full committee meeting will be posted on the Clean Air Act Advisory Committee Web site at *http://www.epa.gov/oar/caaac/.*

Inspection of Committee Documents: The Committee agenda and any documents prepared for the meeting will be publicly available at the meeting. Thereafter, these documents, together with CAAAC meeting minutes, will be available by contacting the Office of Air and Radiation Docket and requesting information under docket EPA–HQ–OAR–2004–0075. The Docket office can be reached by email at: *a-and-r-Docket@epa.gov* or FAX: 202–566–9744.

FOR FURTHER INFORMATION CONTACT: Concerning the CAAAC, please contact Pat Childers, Office of Air and Radiation, U.S. EPA (202) 564–1082, FAX (202) 564–1352 or by mail at U.S. EPA, Office of Air and Radiation (Mail code 6102 A), 1200 Pennsylvania Avenue NW., Washington, DC 20004. For information on the Permits, New Source Review and Toxics subcommittee, please contact Liz Naess at (919) 541–1892. Additional Information on these meetings, CAAAC, and its Subcommittees can be found on the CAAAC Web site: *http://www.epa.gov/oar/caaac/.*

For information on access or services for individuals with disabilities, please contact Mr. Pat Childers at (202) 564–1082 or *childers.pat@epa.gov.* To request accommodation of a disability, please contact Mr. Childers, preferably at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

Dated: February 1, 2013.

Pat Childers,

Designated Federal Official, Clean Air Act Advisory Committee, Office of Air and Radiation.

[FR Doc. 2013–02803 Filed 2–7–13; 8:45 am]

BILLING CODE P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2013–0025; FRL–9376–8]

Notice of Receipt of Pesticide Products; Registration Applications To Register New Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of applications to register new uses for pesticide products containing currently registered active ingredients pursuant to the provisions of section 3(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. This notice provides the public with an opportunity to comment on the applications.

DATES: Comments must be received on or before March 11, 2013.

ADDRESSES: Submit your comments, identified by docket identification (ID) number and the EPA Registration Number or EPA File Symbol of interest as shown in the body of this document, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: A contact person is listed at the end of each registration application summary and may be contacted by telephone, email, or mail. Mail correspondence to the Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001. As part of the mailing address, include the contact person's name, division, and mail code.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Registration Applications

EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the provisions of FIFRA section 3(c)(4), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications. For actions being evaluated under the

Agency's public participation process for registration actions, there will be an additional opportunity for a 30-day public comment period on the proposed decision. Please see the Agency's public participation Web site for additional information on this process (*http://www.epa.gov/pesticides/regulating/registration-public-involvement.html*). EPA received the following applications to register new uses for pesticide products containing currently registered active ingredients:

1. *EPA Registration Numbers:* 264–824 and 264–825. *Docket ID Number:* EPA–HQ–OPP–2012–0876. *Applicant:* Bayer CropScience, 2 T.W. Alexander Drive, P.O. Box 12014, Research Triangle Park, NC 27709. *Active ingredient:* Prothioconazole Technical Fungicide [2-(2–1-Chlorocyclopropyl)-3-(2-chlorophenyl-2-hydroxyproptyl)-1,2-dihydro-3H–1,2,4-triazole-3-thione]. *Product Type:* Fungicide. *Proposed Uses:* Bushberry (crop subgroup 13–07B), low growing berry subgroup, except strawberry (crop subgroup 13–07H and cucurbit vegetables (crop group 9). *Contact:* Rosemary Kearns, RD, (703) 305–5611, email address: *kearns.rosemary@epa.gov.*

2. *EPA Registration Number:* 1001–87. *Docket ID Number:* EPA–HQ–OPP–2013–0017. *Applicant:* Cleary Chemicals, LLC., 178 Ridge Road, Suite A, Dayton, NJ 08810. *Active ingredient:* Tebuconazole. *Product Type:* Fungicide. *Proposed Uses:* Turfgrass use on home lawns, sod and athletic fields. *Contact:* Heather Garvie, RD, (703) 308–0034, email address: *garvie.heather@epa.gov.*

3. *EPA Registration Number:* 7969–278. *Docket ID Number:* EPA–HQ–OPP–2013–0008. *Applicant:* BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709–3528. *Active ingredient:* Saflufenacil. *Product Type:* Herbicide. *Proposed Uses:* Post-emergent applications to rice. *Contact:* Bethany Benbow, RD, (703) 347–8072, email address: *benbow.bethany@epa.gov.*

4. *EPA Registration Numbers:* 59639–35 and 59639–76. *Docket ID Number:* EPA–HQ–OPP–2012–0899. *Applicant:* Valent U.S.A., 1600 Riveria Avenue, Suite 200, Walnut Creek, California 94596. *Active ingredient:* Fenpropathrin. *Product Type:* Insecticide. *Proposed Use:* Barley, fruiting vegetable group 8–10, citrus fruit group 10–10, pome fruit group 11–10, and berry subgroups 13–07 B, F & G. *Contact:* Olga Odiott, RD, (703) 308–9369, email address: *odiott.olga@epa.gov.*

5. *EPA Registration Numbers:* 62719–437 and 62719–442. *Docket ID Number:* EPA–HQ–OPP–2012–0912. *Applicant:* Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268. *Active ingredient:* Methoxyfenozide. *Product Type:* Insecticide. *Proposed Use:* Herb subgroup 19A (except chives), dates, sorghum, peas and bean subgroup 6C (except blackeyed and southern pea), fruiting vegetable group 8–10, pome fruit group 11–10, berry subgroups 13–07 A, F & G, sugar apple, cherimoya, atemoya, custard apple, llama, soursop, and biriba. *Contact:* Olga Odiott, RD, (703) 308–9369, email address*: odiott.olga@epa.gov.*

6. *EPA Registration Numbers:* 62719–519, 62719–572, 62719–628, 62719–629, and 62719–630. *Docket ID Number:* EPA–HQ–OPP–2013–0015. *Applicant:* Dow AgroSciences, 9330 Zionsville Road, Indianapolis, IN 46268. *Active ingredient:* Aminopyralid. *Product Type:* Herbicide. *Proposed Uses:* Weed management in aquatic areas. *Contact:* Bethany Benbow, RD, (703) 347–8072, email address: *benbow.bethany@epa.gov.*

7. *EPA Registration Numbers:* 71049–2 and 71049–4. *Docket ID Number:* EPA–HQ–OPP–2013–0011. *Applicant:* KIM–C1, LLC, 2547 W. Shaw Ave., Suite 116, Fresno, CA 93711. *Active ingredient:* Forchlorfenuron. *Product Type:* Plant Growth Regulator. *Proposed Uses:* Almond; cherry, sweet fig; pear; pistachio; plum; and prune. *Contact:* Cynthia Giles-Parker, RD, (703) 305–7740, email address: *giles-parker.cynthia@epa.gov.*

List of Subjects

Environmental protection, Pesticides and pest.

Dated: February 1, 2013.

Daniel J. Rosenblatt,

Acting, Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2013–02921 Filed 2–7–13; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MARITIME COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Federal Maritime Commission.

TIME AND DATE: February 13, 2013 10:00 a.m.

PLACE: 800 North Capitol Street NW., First Floor Hearing Room, Washington, DC.

STATUS: The meeting will be held in Open Session.

Matters To Be Considered

1. Docket No. 11–22: Non-Vessel-Operating Common Carrier Negotiated Rate Arrangements; Tariff Filing Exemption.

2. Revised Timetable for Retrospective Review of Existing Rules: Priority of Review of Service Contract and Negotiated NVOCC Service Arrangement Rules.

3. Docket No. 11–16: Passenger Vessel Operator Financial Responsibility Requirements for Nonperformance of Transportation and Technical Revision to Passenger Vessel Operator Regulations.

4. Draft Concerning Licensing, Financial Responsibility Requirements, and General Duties for Ocean Transportation Intermediaries.

CONTACT PERSON FOR MORE INFORMATION: Karen V. Gregory, Secretary, (202) 523–5725.

Karen V. Gregory,

Secretary.

[FR Doc. 2013–03052 Filed 2–6–13; 4:15 pm]

BILLING CODE 6730–01–P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act Notice

February 5, 2013.

TIME AND DATE: 2:00 p.m., Thursday, February 21, 2013

PLACE: The Richard V. Backley Hearing Room, Room 511N, 1331 Pennsylvania Avenue NW., Washington, DC 20004 (entry from F Street entrance)

STATUS: Open

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following in open session: *Secretary of Labor* v. *Big Ridge, Inc.,* Docket Nos. LAKE 2009–377, et al. (Issues include whether the Administrative Law Judge erred in determining that certain orders were ''significant and substantial'' and due to the operator's ''unwarrantable failure to comply.'')

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and 2706.160(d).

CONTACT PERSON FOR MORE INFORMATION: Jean Ellen (202) 434–9950/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll free.

Emogene Johnson,

Administrative Assistant.

[FR Doc. 2013–02973 Filed 2–6–13; 11:15 am]

BILLING CODE 6735–01–P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act Notice

February 5, 2013.

TIME AND DATE: 10:00 a.m., Thursday, February 21, 2013.

PLACE: The Richard V. Backley Hearing Room, Room 511N, 1331 Pennsylvania Avenue NW., Washington, DC 20004 (entry from F Street entrance).

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will hear oral argument in the matter *Secretary of Labor* v. *Big Ridge, Inc.,* Docket Nos. LAKE 2009–377, et al. (Issues include whether the Administrative Law Judge erred in determining that certain orders were ''significant and substantial'' and due to the operator's ''unwarrantable failure to comply.'').

Any person attending this oral argument who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and 2706.160(d).

CONTACT PERSON FOR MORE INFORMATION: Jean Ellen (202) 434–9950/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll free.

Emogene Johnson,

Administrative Assistant.

[FR Doc. 2013–02974 Filed 2–6–13; 11:15 am]

BILLING CODE 6735–01–P

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage *de novo,* or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than March 6, 2013.

A. Federal Reserve Bank of San Francisco (Kenneth Binning, Vice President, Applications and Enforcement), 101 Market Street, San Francisco, California 94105–1579:

1. Western Alliance Bancorporation, Phoenix, Arizona; to acquire 100 percent of the voting shares of Centennial Bank, Fountain Valley, California, and thereby engage in operating a savings association, pursuant to section 225.28(b)(4)(i).

Board of Governors of the Federal Reserve System, February 5, 2013.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2013–02865 Filed 2–7–13; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Federal Trade Commission.

ACTION: Notice.

SUMMARY: The information collection requirements described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act (PRA). The FTC seeks public comment on its proposal to extend through May 31, 2016 the current OMB clearance for information collection requirements contained in its Contact Lens Rule. That clearance expires on May 31, 2013.

DATES: Comments must be received by April 9, 2013.

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Request for Comments part of the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be addressed to Alysa S. Bernstein, Attorney, and Bonnie McGregor, Federal Trade Investigator, Division of Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW., Washington, DC 20580, (202) 326–3289 (Bernstein) and (202) 326–2356 (McGregor).

SUPPLEMENTARY INFORMATION:

Proposed Information Collection Activities

Under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501–3520, federal agencies must get OMB approval for each collection of information they conduct, sponsor, or require. ''Collection of information'' means agency requests or requirements to submit reports, keep records, or provide information to a third party. 44 U.S.C. 3502(3); 5 CFR 1320.3(c). As required by section 3506(c)(2)(A) of the PRA, the Federal Trade Commission (FTC) is providing this opportunity for public comment before requesting that OMB extend the existing PRA clearance for the information collection requirements associated with the Commission's Contact Lens Rule (Rule), 16 CFR Part 315 (OMB Control Number 3084–0127).

The FTC invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond. All comments must be received on or before April 9, 2013.

The Rule was promulgated by the FTC pursuant to the Fairness to Contact Lens Consumers Act (FCLCA), Public Law 108–164 (Dec. 6, 2003), which was enacted to enable consumers to purchase contact lenses from the seller of their choice. The Rule became effective on August 2, 2004. As mandated by the FCLCA, the Rule requires the release and verification of contact lens prescriptions and contains recordkeeping requirements applying to both prescribers and sellers of contact lenses.

Specifically, the Rule requires that prescribers provide a copy of the prescription to the consumer upon the completion of a contact lens fitting and verify or provide prescriptions to authorized third parties. The Rule also mandates that a contact lens seller may sell contact lenses only in accordance with a prescription that the seller either: (a) Has received from the patient or prescriber; or (b) has verified through direct communication with the prescriber. In addition, the Rule

imposes recordkeeping requirements on contact lens prescribers and sellers. For example, the Rule requires prescribers to document in their patients' records the medical reasons for setting a contact lens prescription expiration date of less than one year. The Rule requires contact lens sellers to maintain records for three years of all direct communications involved in obtaining verification of a contact lens prescription, as well as prescriptions, or copies thereof, which they receive directly from customers or prescribers.

The information retained under the Rule's recordkeeping requirements is used by the Commission to substantiate compliance with the Rule and may also provide a basis for the Commission to bring an enforcement action. Without the required records, it would be difficult either to ensure that entities are complying with the Rule's requirements or to bring enforcement actions based on violations of the Rule.

Burden Statement

Commission staff estimates the paperwork burden of the FCLCA and Rule based on its knowledge of, and information from, the eye care industry. Staff believes there will be some burden on individual prescribers to provide contact lens prescriptions, although it involves merely writing a few items of information onto a slip of paper and handing it to the patient, or perhaps mailing or faxing it to a third party. In addition, there will be some recordkeeping burden on contact lens sellers—including retaining prescriptions or records of ''direct communications''—pertaining to each sale of contact lenses to consumers who received their original prescription from a third party prescriber.

No substantive provisions in the Rule have been amended or changed since staff's prior submission to OMB.[1] Thus, the Rule's disclosure and recordkeeping requirements remain the same.

Estimated total annual hours burden: 1,770,166 hours.

Based upon staff knowledge of the industry, this figure is derived by adding 633,333 disclosure hours for contact lens prescribers to 1,136,833 recordkeeping hours for contact lens sellers, for a combined industry total of 1,770,166 hours. This is higher than the estimates previously submitted to OMB (the similar figure was 850,000 hours in 2009); and is due to both an increase in the estimated number of contact lens wearers from 34 million (2008) to 38 million (2012) and staff's belief that the percentage of sales in the industry that require obtaining or verifying a prescription is currently higher than what was previously estimated.

As noted above, the number of contact lens wearers in the United States is estimated to be approximately 38 million.[2] Therefore, assuming an annual contact lens exam for each contact lens wearer, approximately 38 million people would receive a copy of their prescription each year under the Rule. At an estimated one minute per prescription, the annual time spent by prescribers complying with the disclosure requirement would be 633,333 hours. [(38 million × 1 minute)/60 minutes = 633,333.3 hours]

As required by the FCLCA, the Rule also imposes two recordkeeping requirements. First, prescribers must document the specific medical reasons for setting a contact lens prescription expiration date shorter than the one year minimum established by the FCLCA. This burden is likely to be nil because the requirement applies only in cases when the prescriber invokes the medical judgment exception, which is expected to occur infrequently, and prescribers are likely to record this information in the ordinary course of business as part of their patients' medical records. The OMB regulation that implements the PRA defines ''burden'' to exclude any effort that would be expended regardless of a regulatory requirement. 5 CFR 1320.3(B)(3)(2).

Second, the Rule requires contact lens sellers to maintain certain documents relating to contact lens sales. As noted above, a seller may sell contact lenses only in accordance with a prescription that the seller either (a) has received from the patient or prescriber, or (b) has verified through direct communication with the prescriber. The FCLCA requires sellers to retain prescriptions and records of communications with prescribers relating to prescription verification for three years.

Staff believes that the burden of complying with this requirement is low. Sellers who seek verification of contact lens prescriptions must retain one or two records for each contact lens sale: Either the relevant prescription itself, or the verification request and any response from the prescriber. Staff estimates that such recordkeeping will entail a maximum of five minutes per sale, including time spent preparing a file and actually filing the record(s).

According to recent survey data, approximately 35.9% of consumers who purchase contacts lenses purchase those lenses from a source other than the doctor who originally wrote the prescription.[3] This means that approximately 13,642,000 consumers—35.9% of the 38 million contact lens wearers in the United States—purchase their lenses from sellers other than the doctor who originally wrote their prescription.

At an estimated five minutes per sale to each of 13.642 million consumers, contact lens sellers will spend a total of 1,136,833 burden hours complying with the recordkeeping requirement. [(13.642 million × 5 minutes)/60 minutes = 1,136,833.3 hours] This estimate likely overstates the actual burden, however, because it includes the time spent by sellers who already keep records pertaining to contact lens sales in the ordinary course of business. In addition, the estimate may overstate the time spent by sellers to the extent that records (*e.g.,* verification requests) are generated and stored automatically and electronically, which staff understands is the case for some larger online sellers.

Estimated labor costs: $48,602,000 (rounded to the nearest thousand).

Commission staff derived labor costs by applying appropriate hourly cost figures to the burden hours described above. Staff estimates, based on information from the industry, that optometrists account for approximately 85% of prescribers. Consequently, for simplicity, staff will focus on their average hourly wage in estimating prescribers' labor cost burden.

According to Bureau of Labor Statistics from May 2011, salaried optometrists earn an average wage of $51.79 per hour and general office clerks earn an average of $13.90 per hour.[4]

With these categories of personnel, respectively, likely to perform the brunt of the disclosure (for optometrists) and recordkeeping (for office clerks) aspects of the Rule, estimated total labor cost attributable to the Rule would be approximately $48.6 million. [($51.79 × 633,333.3 hours) + ($13.90 × 1,136,833.3 hours) = $48,602,314]

The contact lens market is a multibillion dollar market; one recent

[1] The FTC most recently submitted clearance three years ago. 75 FR 19647 (Apr. 15, 2010) and 74 FR 68427 (Dec. 24, 2009).

[2] *See* Jason J. Nichols, Annual Report: Contact Lenses 2012, Contact Lens Spectrum, Jan. 2013, at 24.

[3] *See* VisionWatch, The Vision Council, Contact Lenses, 11A–C (March 2012) (Research Report); VisionWatch, The Vision Council, Contact Lenses, 11A–C (Sept. 2012) (Research Report). The average of the figures given for each six-month period is 35.9%.

[4] Press Release, Bureau of Labor Statistics, United States Department of Labor, Occupational Employment and Wages—May 2011, Table 1 (March 27, 2012), *available at http://www.bls.gov/news.release/ocwage.htm.*

survey estimates that contact lens sales totaled $4,025,500,000 at the retail level between September 2011 and September 2012.[5] Thus, the total labor cost burden estimate of $48.6 million represents approximately 1.2% of the overall market.

Estimated annual non-labor cost burden: $0 or minimal.

Staff believes that the Rule's disclosure and recordkeeping requirements impose negligible capital or other non-labor costs, as the affected entities are likely to have the necessary supplies and/or equipment already (*e.g.,* prescription pads, patients' medical charts, facsimile machines and paper, telephones, and recordkeeping facilities such as filing cabinets or other storage).

Request for Comments

You can file a comment online or on paper. Write ''Contact Lens Rule: FTC File No. P054510'' on your comment. Your comment B including your name and your state B will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which is * * * privileged or confidential,'' as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c). Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, the Commission encourages you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/contactensrulepra,* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov,* you also may file a comment through that Web site.

If you file your comment on paper, write ''Contact Lens Rule: FTC File No. P054510'' on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H–113 (Annex J), 600 Pennsylvania Avenue NW., Washington, DC 20580. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before April 9, 2013. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

Christian S. White,

Acting General Counsel.

[FR Doc. 2013–02823 Filed 2–7–13; 8:45 am]

BILLING CODE 6750–01–P

[5] The Vision Council, Consumer Barometer, 2 (Sept. 2012) (Research Report). The market may, in fact, be larger; this number does not include dollars spent by consumers 17 years of age and younger.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Delegation of Authorities

Notice is hereby given that I have delegated to the Administrator, Centers for Medicare & Medicaid Services (CMS), with authority to re-delegate, the authority vested in the Secretary of the Department of Health and Human Services under Section 1128C(a)(2) of the Social Security Act (the Act) (42 U.S.C. 1320a–7c(a)(2)), as amended, to consult with and arrange for the sharing of data with representatives of health plans pertaining to the Health Care Fraud and Abuse Control Program created by Section 201(a) of the Health Insurance Portability and Accountability Act of 1996 (Section 1128C of the Act; 42 U.S.C. 1320a–7c), as amended.

This delegation excludes any authorities previously assigned or delegated to the Office of Inspector General under Section 1128C (42 U.S.C. 1320a–7c) of the Act.

I hereby affirm and ratify any actions taken by the Administrator, CMS, or other CMS officials, which involve the exercise of this authority prior to the effective date of this delegation.

This delegation of authority is effective upon date of signature.

Authority: 44 U.S.C. 3101.

Dated: February 4, 2013.

Kathleen Sebelius,

Secretary.

[FR Doc. 2013–02900 Filed 2–7–13; 8:45 am]

BILLING CODE 4150–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Full Committee Meeting.

Time and Date: February 28, 2013, 9:00 a.m.–2:45 p.m. EST. March 1, 2013, 9:00 a.m.–11:30 a.m. EST.

Place: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, Rm. 705–A, 200 Independence Avenue SW., Washington, DC 20201.

Status: Open.

Purpose: At this meeting the Committee will hear presentations and hold discussions on several health data policy topics. On the morning of the first day, the Committee will hear updates from the Department (HHS), the Centers for Medicare and Medicaid Services (CMS), the Office of the National Coordinator (ONC), and the Office of Civil Rights (OCR). The Committee will consider plans for 2013 activities and hear from newly appointed Committee members as part of the overview. In preparation for 2013 the Committee will discuss how to maintain the dynamics of working across Subcommittees, as well as how to continue development of its key themes.

In the afternoon, Subcommittee Co-chairs will brief the Committee on plans for a hearing organized by the Population Health Subcommittee to explore aspects of the

Community as a Learning Health System. Committee members will consider ways to implement components of the graphic on the Influences on the Population's Health, in the Shaping a Health Statistics Vision for the 21st Century report. The Co-chairs for the Privacy, Confidentiality and Security Subcommittee will brief the Committee about an upcoming hearing to obtain input about implementing health data stewardship, and the Standards and Quality Subcommittees will also provide updates on plans and activities.

On the morning of the second day, the Committee will continue to discuss ways to promote alignment throughout the Committee to enhance its effectiveness, focus on its themes, and utilize expertise of the NCVHS Working Group on HHS Data Access and Use. Once the full Committee adjourns, the NCVHS's Working Group on HHS Data Access and Use will convene to discuss best practices and suggestions to further the dissemination and use of open HHS data, and summarize future plans of the Working Group. Further information will be provided on the NCVHS Web site at *http://www.ncvhs.hhs.gov/.*

The times shown above are for the full Committee meeting. Subcommittee breakout sessions are scheduled for late in the afternoon on the first day. Agendas for these breakout sessions will be posted on the NCVHS Web site (URL below) when available.

Contact Person for More Information: Substantive program information as well as summaries of meetings and a roster of committee members may be obtained from Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone (301) 458–4245. Information also is available on the NCVHS home page of the HHS Web site: *http://www.ncvhs.hhs.gov/,* where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458–4EEO (4336) as soon as possible.

Dated: January 31, 2013.

James Scanlon,

Deputy Assistant Secretary for Planning and Evaluation, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2013–02830 Filed 2–7–13; 8:45 am]

BILLING CODE 4151–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10419]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New collection (request for a new OMB control number). *Title of Information Collection:* Transparency Reports and Reporting of Physician Ownership or Investment Interests. *Use:* Reports of Payments or Other Transfers of Value to Covered Recipients.

Section 403.904 requires direct and indirect payments or other transfers of value provided by an applicable manufacturer to a covered recipient, and that direct and indirect payments or other transfers of value provided to a third party at the request of (or designated by) the applicable manufacturer on behalf of a covered recipient, be reported by the applicable manufacturer to CMS on an annual basis.

Reports of Physician Ownership and Investment Interests

Under § 403.906, each applicable manufacturer and applicable group purchasing organization must report to CMS on an annual basis all ownership and investment interests in the applicable manufacturer or applicable group purchasing organization that were held by a physician or an immediate family member of a physician during the preceding calendar year.

Data Collection

The data templates will provide detailed information about the data to be collected including the data element name, format, allowable values, required versus optional fields, and other associated rules intended to aid the applicable manufacturers and applicable group purchasing organizations as they prepare for and participate in data collection. Applicable manufacturers and applicable GPOs will engage in data collection external to CMS within their own systems or tracking tools. If we intend to make changes to the data templates, we will provide them at least 90 days prior to first day of data collection for the next reporting year. In providing revised templates, we will also comply with the requirements of the Paperwork Reduction Act to seek public comments on the proposed changes to the information collections, as required by law. This will allow applicable manufacturers and applicable GPOs to make any necessary changes to prepare for the next reporting year. This is the same time as the date by which we will publish the list of teaching hospitals.

Data Submission Procedures for Electronic Submission of Reports

Section 403.908 requires that reports must be electronically submitted to CMS by March 31, 2014, and by the 90th day of each subsequent calendar year. *Form Number:* CMS–10461 (OCN 0938—New). *Frequency:* Annual. *Affected Public:* Private Sector (business or other for-profit and not-for-profit institutions). *Number of Respondents:* 396,514. *Total Annual Responses:* 396,514. *Total Annual Hours:* 13,327,065. (For policy questions regarding this collection contact Erica Breese at 202–260–6079. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by April 9, 2013:

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: February 5, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013–02905 Filed 2–7–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0560]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 11, 2013.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0582. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable—(OMB Control Number 0910–0582)—Extension

FDA's investigational device regulations are intended to encourage the development of new, useful devices in a manner that is consistent with public health, safety, and with ethical standards. Investigators should have freedom to pursue the least burdensome means of accomplishing this goal. However, to ensure that the balance is maintained between product development and the protection of public health, safety, and ethical standards, FDA has established human subject protection regulations addressing requirements for informed consent and institutional review board (IRB) review that apply to all FDA-regulated clinical investigations involving human subjects. In particular, informed consent requirements further both safety and ethical considerations by allowing potential subjects to consider both the physical and privacy risks they face if they agree to participate in a trial.

Under FDA regulations, clinical investigations using human specimens conducted in support of premarket submissions to FDA are considered human subject investigations (see 21 CFR 812.3(p)). Many investigational device studies are exempt from most provisions of part 812, Investigational Device Exemptions, under 21 CFR 812.2(c)(3), but FDA's regulations for the protection of human subjects (21 CFR parts 50 and 56) apply to all clinical investigations that are regulated by FDA (see 21 CFR 50.1, 21 CFR 56.101, 21 U.S.C. 360j(g)(3)(A), and 21 U.S.C. 360j(g)(3)(D)).

FDA regulations do not contain exceptions from the requirements of informed consent on the grounds that the specimens are not identifiable or that they are remnants of human specimens collected for routine clinical care or analysis that would otherwise have been discarded. Nor do FDA regulations allow IRBs to decide whether or not to waive informed consent for research involving leftover or unidentifiable specimens.

In a level 1 guidance document, entitled ''Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable,'' issued under the Good Guidances Practices regulation, 21 CFR 10.115, FDA outlines the circumstances in which it intends to exercise enforcement discretion as to the informed consent regulations for clinical investigators, sponsors, and IRBs.

The recommendations of the guidance impose a minimal burden on industry. FDA estimates that 700 studies will be affected annually. Each study will result in one annual record, estimated to take 4 hours to complete. This results in a total recordkeeping burden of 2,800 hours ($700 \times 4 = 2{,}800$).

In the **Federal Register** of June 12, 2012 (77 FR 34954), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Federal Food, Drug, and Cosmetic Act Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
520(g) (21 U.S.C. 360j(g))	700	1	700	4	2,800

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: February 4, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–02858 Filed 2–7–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–1083]

Draft Guidance for Industry and Food and Drug Administration Staff; Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions.'' This draft guidance provides responses to questions FDA has received regarding the issuance of civil money penalties for violations of regulations issued under the Federal Food, Drug, and Cosmetic Act (FD&C Act) relating to tobacco products in retail outlets. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft by April 9, 2013.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions'' to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Gerie Voss, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373, *gerie.voss@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance provides responses to questions FDA has received regarding the issuance of civil money penalties for violations of regulations issued under the FD&C Act relating to tobacco products in retail outlets. In this draft guidance, FDA provides responses to questions relating to civil money penalties for violations of the requirement that tobacco products may not be sold or distributed in violation of FDA's ''Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents'' (75 FR 13225, March 19, 2010, codified at 21 CFR part 1140). This draft guidance also provides additional information regarding the complaint procedure used for civil money penalties.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on ''Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

An electronic version of the draft guidance document is available on the Internet at *http://www.regulations.gov* and *http://www.fda.gov/Tobacco Products/GuidanceComplianceRegulatoryInformation/default.htm.*

Dated: February 4, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–02861 Filed 2–7–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0077]

Draft Guidance for Industry on Alzheimer's Disease: Developing Drugs for the Treatment of Early Stage Disease; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Alzheimer's Disease: Developing Drugs for the Treatment of Early Stage Disease.'' This guidance outlines FDA's current thinking as to how a sponsor could demonstrate efficacy in clinical trials in patients in the early stages of Alzheimer's disease that occur before the onset of overt dementia.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 9, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nicholas A. Kozauer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4351,

Silver Spring, MD 20993–0002, 301–796–2250.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Alzheimer's Disease: Developing Drugs for the Treatment of Early Stage Disease.'' This guidance outlines FDA's current thinking as to how a sponsor could demonstrate efficacy in clinical trials in patients in the early stages of Alzheimer's disease (AD) that occur before the onset of overt dementia. Specifically, this guidance addresses FDA's current thinking regarding the selection of patients with early AD, or who are determined to be at risk of developing AD, for enrollment into clinical trials. The selection of outcome measures for trials in these populations that are designed to demonstrate a clinical benefit, as well as the manner in which disease modification might be demonstrated, are also addressed. The design of clinical trials that are specifically focused on the treatment of patients with established Alzheimer's disease dementia (i.e., dementia of the Alzheimer's type), or any of the autosomal dominant forms of AD, are not explicitly discussed although many of the principles in this guidance will be pertinent.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on developing drugs for the treatment of early Alzheimer's disease. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: February 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–02863 Filed 2–7–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0448]

International Drug Scheduling; Convention on Psychotropic Substances; World Health Organization Scheduling Recommendations for Gamma-hydroxybutyric Acid

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing interested persons with the opportunity to submit written comments and to request an informal public meeting concerning recommendations by the World Health Organization (WHO) to impose international manufacturing and distributing restrictions, under international treaties, on certain drug substances. The comments received in response to this notice and/or public meeting will be considered in preparing the U.S. position on these proposals for a meeting of the United Nations Commission on Narcotic Drugs (CND) in Vienna, Austria, in March 2013. This notice is issued under the Controlled Substances Act (the CSA).

DATES: Submit either electronic or written comments by February 25, 2013. Submit requests for a public meeting on or before February 19, 2013. (For additional information, see also section IV of this document).

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: James R. Hunter, Center for Drug Evaluation and Research, Controlled Substance Staff, Food and Drug Administration, Bldg. 51, rm. 5150, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3156, email: *james.hunter@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The United States is a party to the 1971 Convention on Psychotropic Substances (the Convention). Section 201(d)(2)(B) of the CSA (21 U.S.C. 811(d)(2)(B)) provides that when the United States is notified under Article 2 of the Convention that CND proposes to decide whether to add a drug or other substance to one of the schedules of the Convention, transfer a drug or substance from one schedule to another, or delete it from the schedules, the Secretary of State must transmit notice of such information to the Secretary of Health and Human Services (Secretary of HHS). The Secretary of HHS must then publish a summary of such information in the **Federal Register** and provide opportunity for interested persons to submit comments. The Secretary of HHS must then evaluate the proposal and furnish a recommendation to the Secretary of State that shall be binding on the representative of the United States in discussions and negotiations relating to the proposal.

As detailed in the following paragraphs, the Secretary of State has received one notification from the Secretary-General of the United Nations (the Secretary-General) regarding substances to be considered for control under the Convention. This notification reflects the recommendation from the 35th WHO Expert Committee for Drug Dependence (ECDD), which met in June 2012. In the **Federal Register** of September 05, 2008 (73 FR 51823), FDA announced the WHO ECDD review and invited interested persons to submit information for WHO's consideration.

The full text of the notification from the Secretary-General is provided in section II of this document. Section 201(d)(2)(B) of the CSA requires the Secretary of HHS, after receiving a notification proposing scheduling, to publish a notice in the **Federal Register** to provide the opportunity for interested persons to submit information and comments on the proposed scheduling action.

II. United Nations Notification

The formal United Nations notification that identifies the drug substance and explains the basis for the recommendations is reproduced as follows:

Reference: NAR/CL.6/2012
WHO/ECDD35 1971C–Art.2
CU 2012/196/DTA/SGB

The Secretary-General of the United Nations presents his compliments to the Secretary of State of the United States of America and has the honour to inform the Government that the Director-

General of the WHO, under article 2, paragraphs 1, 4, and 6, of the Convention on Psychotropic Substances of 1971 (1971 Convention), has notified the Secretary-General that it is of the opinion that Gamma-hydroxybutyric acid (GHB) should be transferred from Schedule IV to Schedule II of the 1971 Convention.

In accordance with the provisions of article 2, paragraph 2, of the 1971 Convention, the Secretary-General hereby transmits the relevant excerpts of the notification as Annex I to the present note. Also in accordance with the same provisions, the notification from WHO will be brought to the attention of the CND at its next session in March 2013.

In connection with the notification, WHO has also submitted excerpts from the report of the Thirty-fifth session of the WHO ECDD (4–8 June 2012) which reviewed the substance. The excerpts from that report concerning GHB are hereby transmitted as Annex II. The excerpts are currently available in English only, pending receipt of the official French translation from the WHO. The report of the Thirty-fifth session of the WHO ECDD can be retrieved from the following Web site: *http://www.who.int/medicines/areas/quality_safety/35thecddmeet/en/index.html.* (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**).

Any action or decision taken by the Commission with respect to this notification, pursuant to article 2, paragraphs 5 and 6, of the 1971 Convention, will be communicated to States Parties in due course. Article 2, paragraphs 5 and 6, reads as follows:

5. The Commission, taking into account the communication from the WHO, whose assessments shall be determinative as to medical and scientific matters, and bearing in mind the economic, social, legal, administrative and other factors it may consider relevant, may add the substance to Schedule I, II, III or IV. The Commission may seek further information from the WHO or from other appropriate sources.

6. If a notification under paragraph 1 relates to a substance already listed in one of the Schedules, the WHO shall communicate to the Commission its new findings, any new assessment of the substance it may make in accordance with paragraph 4 and any new recommendations on control measures it may find appropriate in the light of that assessment. The Commission, taking into account the communication from the WHO as under paragraph 5 and bearing in mind the factors referred to in that paragraph, may decide to transfer the substance from one Schedule to another or to delete it from the Schedules.

To assist the Commission in reaching a decision, it would be appreciated if the Government could communicate any economic, social, legal, administrative, or other factors that it considers relevant to the possible rescheduling under the 1971 Convention, of GHB, at the latest by 28 December 2012 to the Executive Director of the United Nations Office on Drugs and Crime, c/o Secretary, Commission on Narcotic Drugs, P.O. Box 500, 1400 Vienna, Austria, FAX: +43–1–26060–5885, email: *sgb@unodc.org.*

9 November 2012, NAR/CL.6/201, Annex I, Page 1.

Annex I

Relevant excerpts of letter addressed to the Secretary-General of the United Nations by the Director-General of the World Health Organization

''With reference to article 2 of the Convention on Psychotropic Substances (1971), article 2, paragraphs 1, 4 and 6, I am pleased to submit the recommendations of the WHO, concerning the international control of *y*-hydroxybutyric acid (GHB). The recommendation is that GHB be rescheduled from Schedule IV to Schedule II of the 1971 Convention. The basis for this recommendation is set out in an extract from the Report of the ECDD, which advises on these issues, attached to this letter.''

Geneva, 22 October 2012, NAR/CL.6/2012, Annex II, Page 1.

Annex II

Extract From the 35th Report of the Expert Committee on Drug Dependence Recommendation on Gamma-Hydroxybutyric Acid (GHB)

This section provides information in addition to the information presented in the report of the Thirty-fourth meeting. The Expert Committee discussed GHB in the context of Gamma-butyrolactone and 1,4-butanediol (1,4–BD), precursors of GHB, see sections 4.4 and 4.5.

Substance Identification and Pharmacodynamics

Gamma-hydroxybutyric acid (GHB), also known as 4-hydroxybutanoic acid and sodium oxybate, is a naturally occurring substance found in low concentrations in mammalian tissues. It is considered to act by binding to GHB-specific receptors and Gamma-aminobutyric acid B (GABAB) receptors. At pharmacological doses, it acts as a central nervous system depressant.

Previous Reviews

GHB was pre-reviewed during the Thirty-first and Thirty-second meetings, held in 1998 and 2000, respectively. In 2001, GHB was placed in Schedule IV of the 1971 Convention by a decision of the CND. It was again pre-reviewed at the Thirty-fourth ECDD meeting in 2006 (1), at which time the Expert Committee recommended a new critical review to consider GHB's possible rescheduling.

Evidence on Dependence Potential

The Expert Committee examined additional information from the updated critical review report and peer-review reports. The Expert Committee noted that there is compelling evidence that dependence on GHB exists in humans and noted withdrawal syndromes and withdrawal seizures.

Actual Abuse

The Expert Committee noted that at present, GHB appears to be mainly used and abused in the United States of America, Europe and Australia. Most GHB used illicitly originates from clandestine manufacture.

In their discussions, the Expert Committee and advisers agreed on the narrow margin of safety of GHB. There have been numerous reports from Europe and the United States of accidental fatal and non-fatal overdoses where GHB was implicated, both when used alone and with other substances.

The Expert Committee also noted there have been reports of GHB being used to facilitate sexual assault.

Therapeutic Usefulness

GHB is used as a medicine in some countries on a small scale for various indications. GHB is not included in the WHO Model List of Essential Medicines.

Need for the Substance for Other Purposes (e.g., Industrial)

The Expert Committee acknowledged the use of GHB in the production of a wide variety of industrial polymers.

III. Discussion

Although WHO has made specific scheduling recommendations for each of the drug substances, the CND is not obliged to follow the WHO recommendations. Options available to the CND for substances considered for control under the Psychotropic Convention include: (1) Acceptance of the WHO recommendations; (2) acceptance of the recommendations to control, but control the drug substance in a schedule other than that recommended; or (3) reject the recommendations entirely.

GHB is classified as a central nervous system depressant. In 2002, FDA approved a GHB-containing product, Xyrem, for the treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy under the regulations in 21 CFR part 314, subpart H (21 CFR 314.520). Xyrem was included on the list of products deemed to have in effect an approved Risk Evaluation and Mitigation Strategy (REMS) under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1) at the time of the passage of the Food and Drug Administration Amendments Act of 2007 (FDAAA). The REMS for Xyrem includes a medication guide and healthcare provider education brochure, mandatory patient and prescriber certification through enrollment, and restricted dispensing of the drug through a central pharmacy. Xyrem is controlled domestically in Schedule III of the CSA, while bulk GHB and all other material containing GHB are controlled in Schedule I. In addition, illicit use of Xyrem is subject to Schedule I penalties of the CSA. GHB is controlled internationally in Schedule IV of the Psychotropic Convention. The WHO ECDD pre-reviewed GHB at its Thirty-fourth meeting and recommended it for critical review at a future meeting. The WHO ECDD met in Hammamet, Tunisia, from 4–8 June 2012, critically reviewed GHB, and recommended that it be rescheduled from Schedule IV to Schedule II of the Convention on Psychotropic Substances.

IV. Submission of Comments and Opportunity for Public Meeting

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

FDA does not presently plan to hold a public meeting. If any person believes that, in addition to their written comments, a public meeting would contribute to the development of the U.S. position on the substances to be considered for control under the Psychotropic Convention, a request for a public meeting and the reasons for such a request should be sent to James R. Hunter (see **FOR FURTHER INFORMATION CONTACT**) on or before February 19, 2013.

The short time period for the submission of comments and requests for a public meeting is needed to ensure that HHS may, in a timely fashion, carry out the required action and be responsive to the United Nations.

Dated: February 1, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–02859 Filed 2–7–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Therapeutic Hepatitis C Virus Antibodies

Description of Technology: Therapeutic antibodies against Hepatitis C Virus (HCV) have not been very effective in the past and there is evidence that this may result in part from interfering antibodies generated during infection that block the action of neutralizing antibodies. These neutralizing antibodies prevent HCV infection of a host cell.

The subject technologies are monoclonal antibodies against HCV that can neutralize different genotypes of HCV. Both antibodies bind to the envelope (E2) protein of HCV found on the surface of the virus. One of the monoclonal antibodies neutralizes HCV genotype 1a, the most prevalent HCV strain in the U.S., infection and in vitro data show that it is not blocked by interfering antibodies. The second antibody binds a conserved region of E2 and can cross neutralize a number of genotypes including genotypes 1a and 2a. The monoclonal antibodies have the potential to be developed either alone or in combination into therapeutic antibodies that prevent or treat HCV infection. These antibodies may be particularly suited for preventing HCV re-infection in HCV patients who undergo liver transplants; a population of patients that is especially vulnerable to the side effects of current treatments for HCV infection.

Potential Commercial Applications: Therapeutic antibodies for the prevention and/or treatment of HCV infection.

Competitive Advantages

- Therapeutic antibodies have generally fewer side effects than current treatments for HCV infection.
- Potential to be developed into an alternative treatment for HCV infected liver transplant patients, who often cannot tolerate the side effects of current drug treatments.

Development Stage

- Early-stage
- Pre-clinical
- In vitro data available

Inventors: Stephen M. Feinstone, Hongying Duan, Pei Zhang, Marian E. Major, Alla V. Kachko (all of FDA)

Publications

1. Kachko A, et al. New neutralizing antibody epitopes in hepatitis C virus envelope glycoproteins are revealed by dissecting peptide recognition profiles. Vaccine. 2011 Dec 9;30(1):69–77. [PMID 22041300]

2. Duan H, et al. Amino acid residue-specific neutralization and nonneutralization of hepatitis C virus by monoclonal antibodies to the E2 protein. J Virol. 2012 Dec;86(23):12686–94. [PMID 22973024]

Intellectual Property

- HHS Reference No. E–002–2012/0—U.S. Provisional Patent Application No. 61/648,386 filed 17 May 2012
- HHS Reference No. E–167–2012/0—International PCT Application No. PCT/US12/62197 filed 26 Oct 2012

Licensing Contact: Kevin W. Chang, Ph.D.; 301–435–5018; *changke@mail.nih.gov*

Live Attenuated Rubella Vector to Express Vaccine Antigens

Description of Technology: Live attenuated viruses make potent and effective vaccines. Despite the urgent need for an HIV vaccine, this approach has not been feasible because it has not been possible to attenuate the virus reliably and guarantee vaccine safety. Instead, live viral vectors have been proposed that could present HIV vaccine antigens in the most immunogenic way, in the context of an active infection.

The inventors have adapted a rubella vaccine strain as a vector to express HIV and SIV antigen and tested the effect of insert size and composition on vector stability and viral titer. The inventors have identified an acceptor site in the rubella nonstructural gene region, where foreign genes can be expressed as a fusion protein with the nonstructural protein P150 without affecting essential viral functions. The inserts were expressed as early genes of rubella, under control of the rubella genomic promoter. At this site, HIV and SIV antigens were expressed stably for at least seven passages, as the rubella vectors reached high titers. Rubella readily infects rhesus macaques, and these animals will provide an ideal model for testing the new vectors for replication in vivo, immunogenicity and protection against SIV or SHIV challenge.

Potential Commercial Applications

- HIV vaccines
- Bivalent rubella
- Research tools

Competitive Advantages

- Ease of manufacture
- Low cost vaccines

Development Stage

- Pre-clinical
- In vitro data available
- In vivo data available (animal)

Inventors: Ira Berkower and Konstantin Virnik (FDA/CBER)

Publication

Virnik K, et al. Live attenuated rubella viral vectors stably express HIV and SIV vaccine antigens while reaching high titers. Vaccine. 2012 Aug 10;30(37):5453–8. [PMID 22776214]

Intellectual Property

- HHS Reference No. E–004–2012/0—US Application No. 61/621,394, filed 6 Apr 2012
- HHS Reference No. E–004–2012/1—US Application No. 61//642,333 filed 3 May 2012

Related Technologies

- HHS Reference No. E–156–2008/0—US Application No. 13/501,893 filed 13 Apr 2012, claiming priority to 16 Oct 2009
- HHS Reference No. E–291–2008/0—US Application No. 13/057,414 filed 03 Feb 2011, claiming priority to 04 Aug 2008
- HHS Reference No. E–299–2008/0—US Application No. 12/714,085 filed 26 Feb 2010, claiming priority to 26 Feb 2009

Licensing Contact: Peter A. Soukas; 301–435–4646; *soukasp@mail.nih.gov*

DNA Promoters and Anthrax Vaccines

Description of Technology: Currently, the only licensed vaccine against anthrax in the United States is AVA BioThrax®, which, although efficacious, suffers from several limitations. This vaccine requires six injectable doses over 18 months to stimulate protective immunity, requires a cold chain for storage, and in many cases has been associated with adverse effects.

This application claims a modified *B. anthracis* protective antigen (PA) gene for optimal expression and stability, linked it to an inducible promoter for maximal expression in the host, and fused to the secretion signal of the *Escherichia coli* alpha-hemolysin protein (HlyA) on a low-copy-number plasmid. This plasmid was introduced into the licensed typhoid vaccine strain, *Salmonella enterica* serovar Typhi strain Ty21a, and was found to be genetically stable. Immunization of mice with three vaccine doses elicited a strong PA-specific serum immunoglobulin G response with a geometric mean titer of 30,000 (range, 5,800 to 157,000) and lethal-toxin-neutralizing titers greater than 16,000. Vaccinated mice demonstrated 100% protection against a lethal intranasal challenge with aerosolized spores of *B. anthracis* 7702.

Potential Commercial Applications: Anthrax vaccines, therapeutics and diagnostics.

Competitive Advantages

- Vector is well-characterized.
- Simple manufacturing process.
- Potential low-cost vaccine.
- Oral vaccine—avoids needles and can be administered rapidly during emergencies.
- Temperature-stable manufacturing allows for vaccine distribution without refrigeration.

Development Stage

- Pre-clinical
- In vitro data available
- In vivo data available (animal)

Publication

Osorio M, et al. Anthrax protective antigen delivered by Salmonella enterica serovar Typhi Ty21a protects mice from a lethal anthrax spore challenge. Infect Immun. 2009 Apr;77(4):1475–82. [PMID: 19179420]

Intellectual Property: HHS Reference No. E–344–2003/1—

- EP Application No. 04809769.5 filed 20 Sep 2004
- US Patent No. 7,758,855 issued 20 Jul 2010
- US Patent No. 8,247,225 issued 21 Aug 2012
- US Application No. 13/551,168 filed 17 Jul 2012

Licensing Contact: Peter A. Soukas; 301–435–4646; *soukasp@mail.nih.gov*

Collaborative Research Opportunity: The FDA Center for Biologics Evaluation and Research is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize oral anthrax vaccine. For collaboration opportunities, please contact Dr. Dennis J. Kopecko at *dennis.kopecko@fda.hhs.gov* or 301–661–8839.

Live Oral *Shigella Dysenteriae* Vaccine

Description of Technology: This application claims a *Salmonella* typhi Ty21a construct comprising a *Shigella dysenteriae* O-specific polysaccharide (O-Ps) inserted into the Salmonella typhi Ty21a chromosome, where heterologous *Shigella dysenteriae* serotype 1 O-antigen is stably expressed together with homologous *Salmonella* typhi O-antigen. The constructs of this invention elicit immune protection against virulent *Shigella dysenteriae* challenge, as well as *Salmonella* typhi challenge. Also claimed in this application are methods of making the constructs of this invention and methods for inducing an immune response.

Shigella cause millions of cases of dysentery every year, which result in about seven hundred thousand deaths worldwide. *Shigella dysenteriae* serotype 1, one of about forty serotypes of *Shigella,* causes a more severe disease with a much higher mortality rate than other serotypes. There are no licensed vaccines available for protection against *Shigella.* The fact that many isolates exhibit multiple antibiotic resistance complicates the management of dysentery infections.

Potential Commercial Applications

- One component of a multivalent anti-shigellosis vaccine under development.

• Shigella vaccines, therapeutics and diagnostics.

Competitive Advantages

• Vector is well-characterized.
• Simple manufacturing process.
• Potential low-cost vaccine.
• Oral vaccine—avoids need for needles.
• Temperature-stable formulation allows for vaccine distribution without refrigeration.

Development Stage

• Pre-clinical
• In vitro data available
• In vivo data available (animal)

Inventors: Dennis J. Kopecko and De Qi Xu (FDA/CBER)

Publication

Xu DQ, et al. Core-linked LPS expression of Shigella dysenteriae serotype 1 O-antigen in live Salmonella typhi vaccine vector Ty21a: preclinical evidence of immunogenicity and protection. Vaccine. 2007 Aug 14;25(33):6167–75. [PMID 17629369]

Intellectual Property: HHS Reference No. E–214–2004/0—
• EP Application No. 05754091.6 filed 24 May 2005
• EP Application No. 12186545.5 filed 24 May 2005
• US Patent No. 8,071,113 issued 06 Dec 2011
• US Patent No. 8,337,831 issued 25 Dec 2012
• US Application No. 13/687,797 filed 28 Nov 2012

Licensing Contact: Peter A. Soukas; 301–435–4646; *soukasp@mail.nih.gov*

Collaborative Research Opportunity: The FDA Center for Biologics Evaluation and Research is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize combination typhoid-shigellosis oral vaccine. For collaboration opportunities, please contact Dr. Dennis J. Kopecko at *dennis.kopecko@fda.hhs.gov* or 301–661–8839.

Oral Shigellosis Vaccine

Description of Technology: This application claims a *Salmonella* typhi Ty21a construct comprising a *Shigella sonnei* O-antigen biosynthetic gene region inserted into the *Salmonella* typhi Ty21a chromosome, where heterologous *Shigella sonnei* form 1 O-antigen is stably expressed together with homologous *Salmonella* typhi O-antigen. The constructs of this invention elicit immune protection against virulent *Shigella sonnei* challenge, as well as *Salmonella* Typhi challenge. Also claimed in this application are methods of recombineering a large antigenic gene region into a bacterial chromosome.

Bacillary dysentery and enteric fevers continue to be important causes of morbidity in both developed and developing nations. *Shigella* cause greater than one hundred and fifty million cases of dysentery and enteric fever occurs in greater than twenty-seven million people annually. Currently, there is no licensed vaccine to prevent the occurrence of shigellosis. Increasing multiple resistance in *Shigella* commonly thwarts local therapies.

Potential Commercial Applications

• One component of a multivalent Shigellosis vaccine under development
• Research tool

Competitive Advantages

• Low cost production
• Lower cost vaccine
• Oral vaccine—no needles required
• Temperature-stable manufacturing process—avoids need for refrigeration during vaccine distribution

Development Stage

• Pre-clinical
• In vitro data available
• In vivo data available (animal)

Inventors: Dennis J. Kopecko and Madushini N. Dharmasena (FDA/CBER)

Publication

Dharmasena MN, et al. Stable Expression of Shigella sonnei Form I O-Polysaccharide Genes Recombineered into the Chromosome of Live Salmonella Oral Vaccine Vector Ty21a. Int J Med Microbiol. 2013 (accepted).

Intellectual Property: HHS Reference No. E–168–2012/0—US Application No. 61/701,939 filed 17 Sep 2012

Licensing Contact: Peter A. Soukas; 301–435–4646; *soukasp@mail.nih.gov*

Collaborative Research Opportunity: The FDA Center for Biologics Evaluation and Research is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize oral Shigellosis vaccine. For collaboration opportunities, please contact Dr. Dennis J. Kopecko at *dennis.kopecko@fda.hhs.gov* or 301–661–8839.

Dated: February 1, 2013.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2013–02834 Filed 2–7–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Beta-Cell Function and Cognition.
Date: March 4, 2013.
Time: 3:00 p.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Barbara A. Woynarowska, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 754, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 402–7172, *woynarowskab@niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK R24 SEP.
Date: March 4, 2013.
Time: 12:30 p.m. to 1:30 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institute of Health, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Xiaodu Guo, MD, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 761, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–4719, *guox@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Liver Related Ancillary Studies.
Date: March 13, 2013
Time: 1:30 p.m. to 3:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Paul A. Rushing, Ph.D., Scientific Review Officer, Review Branch,

DEA, NIDDK, National Institutes of Health, Room 747, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8895, *rushingp@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Limited Competition for the Continuation of Look AHEAD (Action for Health in Diabetes) Consortium (U01)-RFA–DK12–502.

Date: March 14, 2013.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894, *begumn@niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK Ancillary Studies.

Date: March 15, 2013.

Time: 10:30 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Thomas A. Tatham, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 760, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–3993, *tathamt@mail.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Limited Competition Acute Kidney Injury.

Date: March 20, 2013.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Robert Wellner, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 706, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301–594–4721, *rw175w@nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; R24 Collaborative Interdisciplinary Team Science–3.

Date: March 27, 2013.

Time: 1:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Ann A. Jerkins, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes Of Health, Room 759, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301–594–2242, *jerkinsa@niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; R24 Collaborative Interdisciplinary Team Science–8.

Date: April 1, 2013.

Time: 2:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Ann A. Jerkins, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 759, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301–594–2242, *jerkinsa@niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; R24 Collaborative Interdisciplinary Team Science—1.

Date: April 2, 2013.

Time: 2:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Ann A. Jerkins, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 759, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301–594–2242, *jerkinsa@niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: February 1, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–02836 Filed 2–7–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Cancer Institute Director's Consumer Liaison Group.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Cancer Institute Director's Consumer Liaison Group

Date: March 18–19, 2013

Time: 9:00 a.m. to 1:00 p.m.

Agenda: March 18, 2013—Informed Consent for Genomic Research;March 19, 2013, March 18, 2013In—formed Consent for Genomic Research;

Place: National Institutes of Health, Building 31, C Wing, 6th Floor, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Kelli Marciel, Director, Office of Advocacy Relations, National Cancer Institute, National Institutes of Health, 31 Center Drive, Building 31, Room 10A28, Bethesda, MD 20892, 301–594–3194.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *deainfo.nci.nih.gov/advisory/dclg/dclg.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer CentersSupport; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 4, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–02837 Filed 2–7–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health; Disparities Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is

hereby given of a meeting of the National Advisory Council on Minority Health and Health Disparities.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Minority Health and Health Disparities.

Date: February 26, 2013.

Closed: 8:00 a.m. to 9:30 a.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, National Institute on Minority Health and Health Disparities, 6707 Democracy Blvd., Rm. 849, Bethesda, MD 20892.

Open: 9:30 a.m. to 5:00 p.m.

Agenda: The agenda will include opening remarks, administrative matters, Director's Report, NIH Health Disparities update, and other business of the Council.

Place: National Institutes of Health, National Institute on Minority Health and Health Disparities, 6707 Democracy Blvd., Rm. 849, Bethesda, MD 20892.

Contact Person: Donna Brooks, Executive Officer, National Institutes of Health, National Institute on Minority Health and Heath Disparities, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20892, (301) 435–2135, *brooksd@ncmhd.nih.gov.*

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Dated: February 4, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–02842 Filed 2–7–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; CALERIE Dataset.

Date: March 7, 2013.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Room 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Rebecca J. Ferrell, Ph.D., Scientific Review Officer, National Institute on Aging, Gateway Building, Room 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–402–7703, *ferrellrj@mail.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel; Health and Aging Trends.

Date: March 7, 2013.

Time: 4:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: DoubleTree by Hilton Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814, (Teleconference).

Contact Person: Jeanette L. Johnson, Ph.D., Scientific Review Officer, National Institute on Aging, National Institutes of Health, Gateway Building, Room 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–402–7705, *johnsonj9@nia.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: February 4, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–02838 Filed 2–7–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel; NEI Core Grant (P30) Applications and Training Grant (K) Applications.

Date: March 8, 2013.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892.

Contact Person: Anne E Schaffner, Ph.D., Chief, Scientific Review Branch, Division of Extramural Research, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, MSC 9300, 301–451–2020, *aes@nei.nih.gov.*

Name of Committee: National Eye Institute Special Emphasis Panel; NEI Clinical Applications.

Date: March 11, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892.

Contact Person: Brian Hoshaw, Ph.D., Scientific Review Officer, Division of Extramural Research, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, MSC 9300, 301–451–2020, *hoshawb@mail.nih.gov.*

Name of Committee: National Eye Institute Special Emphasis Panel; NEI Clinical Applications.

Date: March 14, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn, 7301 Waverly Street, Bethesda, MD 21045.

Contact Person: Jeanette M Hosseini, Ph.D., Scientific Review Officer, Division of Extramural Research, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, MSC 9300, 301–451–2020, *jeanetteh@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: February 4, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–02841 Filed 2–7–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Development of Medical Countermeasures for Post-Exposure Mitigation/Treatment of Injuries Resulting From a Radiation/Nuclear Incident (U01).

Date: March 6–7, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Silver Spring Hotel, 8777 Georgia Avenue, Silver Spring, MD 20910.

Contact Person: Lakshmi Ramachandra, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, Room 3264, Bethesda, MD 20892–7616, 301–402–5658, *ramachandral@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: February 1, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–02835 Filed 2–7–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Fellowships and Dissertation Grants.

Date: March 4, 2013.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person:, Marina Broitman, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6153, MSC 9608, Bethesda, MD 20892–9608, 301–402–8152, *mbroitma@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Intervention Conflicts Panel.

Date: March 6, 2013.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Aileen Schulte, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–1225, *aschulte@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; R34 HIV/AIDS Interventions and Services.

Date: March 7, 2013.

Time: 11:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: David W. Miller, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive BLVD., Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–9734, *millerda@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: February 4, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–02839 Filed 2–7–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; SBIB Pediatric and Fetal Applications.

Date: February 26, 2013.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: John Firrell, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5118, MSC 7854, Bethesda, MD 20892, 301–435–2598, *firrellj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Population

Sciences and Epidemiology: Member Conflict Applications.

Date: March 4–5, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Karin F Helmers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, MSC 7770, Bethesda, MD 20892, 301–254–9975, *helmersk@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel;Population Sciences and Epidemiology: Member Conflict Applications

Date: March 4–5, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Karin F Helmers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, MSC 7770, Bethesda, MD 20892, 301–254–9975, *helmersk@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–10–244: The Collaborative Genetic Study of Nicotine Dependence.

Date: March 5–6, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting)

Contact Person: Eugene Carstea, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 408–9756, *carsteae@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Development of Appropriate Pediatric Formulations and Pediatric Drug Delivery System.

Date: March 5, 2013.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Robert C Elliott, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3130, MSC 7850, Bethesda, MD 20892, 301–435–3009, *elliotro@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: NanoImaging Center.

Date: March 5–7, 2013.

Time: 6:00 p.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Joseph Thomas Peterson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301–408–9694, *petersonjt@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846- 93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: February 4, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–02840 Filed 2–7–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Agency Information Collection Activities: Request for Expressions of Interest (EOI) To Perform a Chemical Defense Demonstration Project

AGENCY: Office of Health Affairs Chemical Defense Program, DHS.

ACTION: 60-Day Notice and request for comments; New Collection, 1601—NEW.

SUMMARY: The Department of Homeland Security, Office of Health Affairs Chemical Defense Program, will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35).

DATES: Comments are encouraged and will be accepted until April 9, 2013. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Written comments and questions about this Information Collection Request should be forwarded to Office of Health Affairs Chemical Defense Program, DHS, Attn.: CAPT Joselito Ignacio, *joselito.ignacio@hq.dhs.gov*, 202–254–5738.

SUPPLEMENTARY INFORMATION: The Chemical Defense Program seeks to obtain information from respondents interested in hosting a demonstration project aimed at developing a comprehensive chemical defense framework. The authority for the Chemical Defense Program to collect this information can be found in Public Law 112–74, Consolidated Appropriations Act, 2012 and Conference Report 112–331.

The information requested on the form includes: name of state, local, tribal, or territorial government agency; address; submitter's name, position and contact information; identified venue for demonstration project; interest in developing a chemical defense capability; specific reasons for the communities interest and needs for a chemical defense capability; community chemical threat assessed risks if applicable; any additional information respondent requests for consideration. As identified in Public Law 112–74 and Conference Report 112–331, the Chemical Defense Program must competitively select the locations for conducting the chemical defense demonstration projects. The Chemical Defense Program will use the provided information for the selection process. The Office of Management and Budget is particularly interested in comments which:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Analysis

Agency: Office of Health Affairs Chemical Defense Program, DHS.

Title: Request for Expressions of Interest (EOI) To Perform a Chemical Defense Demonstration Project.

OMB Number: 1601–NEW.

Frequency: Once.

Affected Public: State, Local, or Tribal Government.

Number of Respondents: 25.

Estimated Time Per Respondent: 20 hours.

Total Burden Hours: 500 Hours.

Dated: January 29, 2013.

Richard Spires,

Chief Information Officer.

[FR Doc. 2013–02886 Filed 2–7–13; 8:45 am]

BILLING CODE 9110–9B–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2012–0867]

Southwest Louisiana Area Maritime Security Regional Sub-Committee; Vacancies

AGENCY: Coast Guard, DHS.

ACTION: Solicitation for Membership.

SUMMARY: This notice requests that individuals interested in serving on the Southwest Louisiana Area Maritime Security Regional Sub-Committee of the Sabine-Neches Area Maritime Security Committee, a committee under the jurisdiction of the Federal Maritime Security Coordinator (FMSC), Marine Safety Unit Port Arthur Texas, submit their applications for membership to the Captain of the Port (COTP), Port Arthur, TX.

DATES: Requests for membership should reach the U.S. Coast Guard COTP Port Arthur March 11, 2013.

ADDRESSES: Requests for membership should be submitted to the COTP Port Arthur at the following address: Commanding Officer, Marine Safety Unit (MSU) Lake Charles, One Lakeside Plaza, Suite 200, 127 West Broad Street, Lake Charles, LA 70601 or by email to *Robyn.A.Kapperman@uscg.mil.*

FOR FURTHER INFORMATION CONTACT: For questions about submitting an application or about the Area Maritime Security Committee (AMSC) in general, please contact MSU Lake Charles Port Security Specialist Dr. Robyn A. Kapperman at (337) 721–5763.

SUPPLEMENTARY INFORMATION:

Authority

Section 102 of the Maritime Transportation Security Act (MTSA) of 2002 (Pub. L. 107–295) added section 70112 to Title 46 of the U.S. Code and authorized the Secretary of the Department in which the Coast Guard is operating to establish AMSCs for any port area of the United States. (See 33 U.S.C. 1226; 46 U.S.C. 70112; 33 CFR 1.05–1, 6.01; Department of Homeland Security Delegation No. 0170.1). The MTSA includes a provision exempting these AMSCs from the Federal Advisory Committee Act (FACA), Public Law 92–436, 86 Stat. 470(5 U.S.C. App.2).

Southwest Louisiana Area Maritime Security Regional Sub-Committee Purpose

AMSCs assist the FMSC in the development, review, update, and exercising of the Area Maritime Security (AMS) Plan for their area of responsibility. Such matters may include, but are not limited to: (1) Identifying critical port infrastructure and operations; (2) identifying risks (threats, vulnerabilities, and consequences); (3) determining mitigation strategies and implementation methods; (4) developing and describing the process to continually evaluate overall port security by considering consequences and vulnerabilities, how they may change over time, and what additional mitigation strategies can be applied; and (5) providing advice, and assisting the FMSC in developing and maintaining the AMS Plan.

AMSC Composition

The composition of the Sabine Neches AMSC, to include the Southwest Louisiana AMS Regional Sub-Committee, is controlled by 33 CFR 103.305. Accordingly, members may be selected from the Federal, Territorial, or Tribal government; the State government and political subdivisions of the State; local public safety, crisis management, and emergency response agencies; law enforcement and security organizations; maritime industry, including labor; other port stakeholders having a special competence in maritime security; and port stakeholders affected by security practices and policies. Also, members of the AMSC must have at least 5 years of experience related to maritime or port security operations.

AMSC Membership

The Southwest Louisiana AMS Sub-Committee is a regional sub-committee of the Sabine-Neches AMSC and is comprised of individuals who represent Federal, State, local, and industry stakeholder interests in the Calcasieu River Region. We are seeking to fill up to ten (10) positions, including one executive committee position and nine alternate committee positions, with this solicitation.

Applicants may be required to pass an appropriate security background check prior to appointment to the committee. Members' terms of office will range from one year to five years; however, a member is eligible to serve additional terms of office. Members will not receive any salary or other compensation for their service on an AMSC.

Request for Applications

Those seeking membership are not required to submit formal applications to the local COTP; however, we have an obligation to ensure that a specific number of members have the prerequisite maritime security experience, therefore we encourage the submission of resumes highlighting experience in the maritime, response, and security industries.

Dates of employment and points of contact should be included for each position highlighted in the resume.

In support of the policy of the Coast Guard on gender and ethnic nondiscrimination, we encourage qualified men and women and members of all racial and ethnic groups to apply. The Coast Guard values diversity; all the different characteristics and attributes of persons that enhance the mission of the Coast Guard.

Dated: November 30, 2012.

G.J. Paitl,

Captain, U.S. Coast Guard, Federal Maritime Security Coordinator Port Arthur.

[FR Doc. 2013–02860 Filed 2–7–13; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2013–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

DATES: The effective date of May 16, 2013 which has been established for the FIRM and, where applicable, the supporting FIS report showing the new

or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *www.msc.fema.gov* by the effective date indicated above.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Deputy Associate Adminstrator for Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

Community	Community map repository address
Ottawa County, Michigan (All Jurisdictions) Docket No.: FEMA–B–1242	
Charter Township of Allendale	Township Office, 6676 Lake Michigan Drive, Allendale, MI 49401.
Charter Township of Georgetown	Georgetown Township Office, 1515 Baldwin Street, Jenison, MI 49428.
Charter Township of Tallmadge	Tallmadge Township Office, O–1451 Leonard Street Northwest, Grand Rapids, MI 49534.
Oneida County, Wisconsin, and Incorporated Areas Docket No.: FEMA–B–1246	
City of Rhinelander	City Hall, 135 South Stevens Street, Rhinelander, WI 54501.
Lac Du Flambeau Band of Lake Superior Chippewa Indians	William Wildcat Tribal Community Building, 418 Little Pines Road, Lac du Flambeau, WI 54538.
Unincorporated Areas of Oneida County	Oneida County Offices, 1 South Oneida Avenue, Rhinelander, WI 54501.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

James A. Walke,

Acting Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2013–02815 Filed 2–7–13; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5683–N–11]

Notice of Submission of Proposed Information Collection to OMB HOME Investment Partnerships Program

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

The information collected through HUD's Integrated Disbursement and Information System (IDIS) (§ 92.502) is used by HUD Field Offices, HUD Headquarters and HOME Program Participating Jurisdictions (PJs). The information on program funds committed and disbursed is used by HUD to track PJ performance and to determine compliance with the statutory 24-month commitment deadline and the regulatory 5-year expenditure deadline (§ 92.500(d)). The project-specific property, tenant, owner and financial data is used to compile annual reports to Congress required at Section 284(b) of the Act, as well as to make program management decisions about how well program participants are achieving the statutory objectives of the HOME Program. Program management reports are generated by IDIS to provide data on the status of program participants' commitment and disbursement of HOME funds. These reports are provided to HUD staff as well as to HOME PJs. Management reports required in conjunction with the Annual Performance Report (§ 92.509) are used by HUD Field Offices to assess the effectiveness of locally designed programs in meeting specific statutory requirements and by Headquarters in preparing the Annual Report to Congress. Specifically, these reports permit HUD to determine compliance with the requirement that PJs provide a 25% match for HOME funds expended during the Federal fiscal year (Section 220 of the Act) and that program income be used for HOME eligible activities (Section 219 of the Act), as well as the Women and Minority Business Enterprise requirements (§ 92.351(b)). Financial, project, tenant and owner documentation is used to determine compliance with HOME Program cost limits (Section 212(e) of the Act), eligible activities (§ 92.205), and eligible costs (§ 92.206), as well as to determine whether program participants are lenders on their overall program performance. The information collected is used to determine insurance eligibility and claim eligibility.

DATES: *Comments Due Date: March 11, 2013.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2506–0171) and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov* fax: 202–395–5806.

FOR FURTHER INFORMATION CONTACT: Colette Pollard., Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov.* or telephone (202) 402–3400. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that the Department of Housing and Urban Development has submitted to OMB a request for approval of the Information collection described below. This notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This notice also lists the following information:

Title of Proposed: HOME Investment Partnerships Program.

OMB Approval Number: 2506–0171.

Form Numbers: HUD 40093, SF 1199A, HUD 20755, HUD 40107, HUD 401107A.

Description of the need for the information and proposed use: The information collected through HUD's Integrated Disbursement and Information System (IDIS) (§ 92.502) is used by HUD Field Offices, HUD Headquarters and HOME Program Participating Jurisdictions (PJs). The information on program funds committed and disbursed is used by HUD to track PJ performance and to determine compliance with the statutory 24-month commitment deadline and the regulatory 5-year expenditure deadline (§ 92.500(d)). The project-specific property, tenant, owner and financial data is used to compile annual reports to Congress required at Section 284(b) of the Act, as well as to make program management decisions about how well program participants are achieving the statutory objectives of the HOME Program. Program management reports are generated by IDIS to provide data on the status of program participants' commitment and disbursement of HOME funds. These reports are provided to HUD staff as well as to HOME PJs. Management reports required in conjunction with the Annual Performance Report (§ 92.509) are used by HUD Field Offices to assess the effectiveness of locally designed programs in meeting specific statutory requirements and by Headquarters in preparing the Annual Report to Congress. Specifically, these reports permit HUD to determine compliance with the requirement that PJs provide a 25% match for HOME funds expended during the Federal fiscal year (Section 220 of the Act) and that program income be used for HOME eligible activities (Section 219 of the Act), as well as the Women and Minority Business Enterprise requirements (§ 92.351(b)). Financial, project, tenant and owner documentation is used to determine compliance with HOME Program cost limits (Section 212(e) of the Act), eligible activities (§ 92.205), and eligible costs (§ 92.206), as well as to determine whether program participants are lenders on their overall program performance. The information collected is used to determine insurance eligibility and claim eligibility.

Status: Reinstatement without change of a predviously approved collection.

	Number of respondents	Annual responses	×	Hours per response	Burden hours
Reporting Burden	644	326		2.489	522,762

Total Estimated Burden Hours: 522,762.

Status: Reinstatement without change of a previously approved collection.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: February 4, 2013.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2013–02813 Filed 2–7–13; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5681–N–06]

Federal Property Suitable as Facilities to Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the

December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Theresa Ritta, Division of Property Management, Program Support Center, HHS, room 5B–17, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Ann Marie Oliva at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (i.e., acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: ARMY: Ms. Veronica Rines, Department of Army, Office of the Chief of Staff for Installation Management, 600 Army Pentagon, Room 5A128, Washington, DC 20310, (571)–256–8145; (This is not a toll-free number).

Dated: January 31, 2013.

Mark Johnston,

Deputy Assistant Secretary for Special Needs.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM, FEDERAL REGISTER REPORT FOR 02/08/2013

Unsuitable Properties

BUILDING

North Carolina

Buildings 6036 & 7556
4030 & 4551 Normandy Dr.
Ft. Bragg NC 28310
Landholding Agency: Army
Property Number: 21201310032
Status: Underutilized
Comments: located w/in military reservation; public access denied & no alternative method to gain access w/out compromising nat'l security.
Reasons: Secured Area

[FR Doc. 2013–02501 Filed 2–7–13; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–ES–2013–N033; FXES11130300000–134–FF03E00000]

Endangered and Threatened Wildlife and Plants; Draft Revised Indiana Bat Summer Survey Guidelines

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; extension of comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (USFWS), are extending the public comment period on documents related to the draft revised summer survey guidelines for the Indiana bat (*Myotis sodalis*) for an additional 30 days. We announced availability of these documents in our January 9, 2013, **Federal Register** notice, which opened a 30-day public comment period. If you have previously submitted comments, you do not need to resubmit them. We have already incorporated them in the public record and will fully consider them in our final USFWS guidelines. The draft guidelines were prepared by representatives of the U.S. Department of Agriculture's Forest Service, U.S. Department of Defense's Army Corps of Engineers, U.S. Department of the Interior's Geological Survey and USFWS, Kentucky Department of Fish and Wildlife Resources, New York State Department of Environmental Conservation, and the Indiana Department of Natural Resources. We request review and comment on the guidelines—along with acoustic identification software testing criteria our 2013 contingency plan—from local, State, and Federal agencies and the public.

DATES: To ensure consideration, please send your written comments on or before March 11, 2013.

ADDRESSES: *Obtaining Documents:* The draft survey guidelines, acoustic identification software testing criteria, and 2013 contingency plan are available at *http://www.fws.gov/midwest/Endangered/mammals/inba/inbasummersurveyguidance.html.* The documents are also available by request, by U.S. mail from the U.S. Fish and Wildlife Service, Ecological Services Field Office, 620 South Walker Street, Bloomington, IN 47403–2121; or by phone at 812–334–4261, x1216.

Submitting Comments: If you wish to comment on the documents, you may submit your comments in writing by any one of the following methods:

- *U.S. mail:* U.S. Fish and Wildlife Service, 620 South Walker Street, Bloomington, IN 47403–2121;
- *Hand-delivery:* Field Supervisor at the above U.S. mail address;
- *Email: indiana_bat@fws.gov*; or
- *Fax:* 812–334–4273. Include ''Indiana Bat Summer Survey Guidelines'' in the subject line of the facsimile transmittal.

FOR FURTHER INFORMATION CONTACT: Questions or requests for additional information may be directed to any of the following: (1) Mr. Andrew King, Endangered Species Biologist, at the Bloomington, Indiana, Field Office address or phone above; (2) Ms. Robyn Niver, Endangered Species Biologist, by U.S. mail at U.S. Fish and Wildlife Service, Ecological Services Field

Office, 3817 Luker Road, Cortland, NY 13045; or by phone at 607–753–9334; or (3) Mr. Mike Armstrong, Endangered Species Biologist, by U.S. mail at U.S. Fish and Wildlife Service, Ecological Services Field Office, J.C. Watts Federal Building, Room 265, 330 West Broadway, Frankfort, KY 40601–8670; or by phone at 502–229–4632.

SUPPLEMENTARY INFORMATION:

Background

The Indiana bat was originally listed as in danger of extinction under the Endangered Species Preservation Act of 1966. It was subsequently listed as endangered under the Endangered Species Act of 1973, as amended. Summer survey guidelines (mist-netting protocols) were first developed for the species in the early 1990s and the USFWS provided revised mist-netting guidelines in our 2007 Draft Revised Recovery Plan. The USFWS recently convened a group of State and Federal agency representatives to revise existing survey guidelines. We solicited peer review through the bat working groups across the range of the Indiana bat between February and March 2012 and received comments from 57 individuals. Based upon comments received and the results of pilot testing of the survey guidelines at known Indiana bat maternity colonies in the summer of 2012, we offer the revised guidelines for public review and comment.

In addition to soliciting comments on draft survey guidelines for determining presence or probable absence of Indiana bats in the summer, we request comment on our proposed approach and criteria for testing the accuracy and suitability of available acoustic identification software programs. Only programs that pass our suitability test would be approved by the USFWS for official survey use. Our goal is to incorporate comments and finalize the draft survey guidelines and testing criteria in time for implementation in the 2013 field season. However, should no USFWS-approved software programs be concurrently available, we propose to follow an intermediary contingency plan. The draft survey guidelines, draft acoustic identification software testing criteria, and 2013 contingency plan, with instructions for commenting, are available on the Internet (see **ADDRESSES**).

Request for Public Comments

We invite written comments on (1) The draft survey guidelines, (2) the acoustic identification software testing criteria, and (3) the 2013 contingency plan. Substantive comments may or may not result in changes to the USFWS guidance document. Please include sufficient information with your comments to allow us to verify any scientific or commercial information you include.

While all comments we receive will be considered in developing final documents, we encourage commenters to focus on those portions of the guidelines that have been revised, particularly those topics noted above that address peer-review comments. If you have previously submitted comments, you need not resubmit them because we have already incorporated them in the public record and will fully consider them in our final USFWS summer survey guidelines for the Indiana bat.

All comments received by the date specified in **DATES** will be considered in preparing final documents. Methods of submitting comments are in **ADDRESSES**.

Public Availability of Comments

Responses to individual commenters will not be provided; however, we will provide the comments we receive and a summary of how we addressed substantive comments in a frequently asked questions document on the Web site listed above. If you submit comments or information by email to *indiana_bat@fws.gov*, your entire submission—including any personal identifying information—will be posted on the Web site. If your submission is made by hard copy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hard copy and email submissions on the Web site listed above in **ADDRESSES**.

Comments and materials we receive will be available on our Web site; however, individuals without internet access may request an appointment to inspect the comments during normal business hours at our office in Bloomington, Indiana (see **ADDRESSES**).

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 et seq.).

Dated: February 4, 2013.

Sean O. Marsan,

Acting Assistant Regional Director, Ecological Services, Midwest Region.

[FR Doc. 2013–02889 Filed 2–7–13; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R2–R–2012–N277; FXRS1265022CCP0–134–FF02R06000]

Ozark Plateau National Wildlife Refuge; Adair, Cherokee, Craig, Delaware, Mayes, Ottawa, and Sequoyah Counties, OK; Draft Comprehensive Conservation Plan and Environmental Assessment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the availability of a draft comprehensive conservation plan (Draft CCP) and an environmental assessment (EA) for Ozark Plateau National Wildlife Refuge (NWR), which is located within the approved acquisition area of Adair, Cherokee, Craig, Delaware, Mayes, Ottawa, and Sequoyah Counties of Oklahoma, for public review and comment. The Draft CCP/EA describes our proposal for managing the Refuge for the next 15 years.

DATES: To ensure consideration, please send your written comments by March 8, 2013. Public meetings will be hosted on Monday, February 25th at the Delaware County Library, in Jay, OK 74346; Tuesday, February 26th at the Stilwell Community Center in Stilwell, OK; and Thursday, Februay 28th in the Community Ballroom of the Cherokee Nation Tribal Headquarters in Tahlequah, OK. All three meetings will begin at 5:30 p.m.

ADDRESSES: You may submit comments or requests for copies or more information on the Draft CCP/EA by any of the methods listed below. You may request hard copies or a CD–ROM of the Draft CCP/EA documents. Please contact Sarah Catchot, Lead Planner, or Shea Hammond, Refuge Wildlife Specialist.

Email: sarah_catchot@fws.gov. Include ''Ozark Plateau NWR Draft CCP and EA'' in the subject line of the message.

U.S. Mail: Sarah Catchot, Lead Planner, U.S. Fish and Wildlife Service, NWRS Division of Planning, P.O. Box 1306, Albuquerque, NM 87103.

FOR FURTHER INFORMATION CONTACT: Shea Hammond, Refuge Wildlife Specialist of Ozark Plateau National Wildlife Refuge, 16602 County Road 465, Colcord, OK 74338, Phone: 918–326–0156.

SUPPLEMENTARY INFORMATION:

Introduction

With this notice, we continue the CCP process for the Ozark Plateau National Wildlife Refuge. We started this process through a notice in the **Federal Register** on June 19, 1998 (63 FR 33693).

The Refuge manages several units scattered throughout its seven-county (Adair, Cherokee, Craig, Delaware, Mayes, Ottawa, and Sequoyah) approved acquisition area in northeastern Oklahoma. Management units of Ozark Plateau NWR are identified, acquired, and/or managed based upon impact to federally listed threatened or endangered Ozark cave species, including cave habitat, groundwater recharge areas, foraging areas, and movement corridors important to these species as well as other species of concern. In addition, Ozark Plateau NWR's management units play a role in conserving continuous tracts of mature oak-hickory or oak-hickory-pine Ozark forest, beneficial to nesting and migrating Neotropical birds as well as cave species.

Background

The CCP Process

The National Wildlife Refuge System Administration Act of 1966 (16 U.S.C. 668dd–668ee) (Refuge Administration Act), as amended by the National Wildlife Refuge System Improvement Act of 1997, requires us to develop a CCP for each national wildlife refuge. The purpose for developing a CCP is to provide refuge managers with a 15-year plan for achieving refuge purposes and contributing toward the mission of the National Wildlife Refuge System, consistent with sound principles of fish and wildlife management, conservation, legal mandates, and our policies. In addition to outlining broad management direction on conserving wildlife and their habitats, CCPs identify wildlife-dependent recreational opportunities available to the public, including opportunities for wildlife observation and photography, and environmental education and interpretation. We will review and update the CCP at least every 15 years in accordance with the Refuge Administration Act.

Public Outreach

Formal scoping began with publication of a notice of intent to prepare a comprehensive conservation plan and environmental assessment in the **Federal Register** on June 19, 1998 (63 FR 33693). The Refuge solicited public comments on issues and concerns to aid in CCP development through three open house meetings held in December 2009 at Tribal Headquarters of the Cherokee Nation in Tahlequah, the Senior Center in Stilwell, and the Delaware County Library in Jay, Oklahoma.

The Refuge also met on March 3, 2010, with the Cherokee Nation Environmental Protection Commission at the Cherokee Nation Headquarters to understand issues concerning the tribe and discuss potential ways to collaborate on solving issues common to the two agencies. On March 4, 2010, the Refuge met with the Oklahoma Department of Wildlife Conservation staff at the Porter Office in Oklahoma also to discuss their concerns regarding past management, future management, and issues common to both agencies.

The feedback received at the conclusion of the public scoping period identified numerous concerns from a variety of stakeholders. These concerns were organized by the following seven broad issue categories: Landscape-level, Habitat Management, Wildlife Management, Public Use Opportunities, Cultural Resources, Facilities & Infrastructure, and Administration.

CCP Alternatives We Are Considering

During the public scoping process with which we started work on this Draft CCP, we, other Federal agencies, Tribal Nations, State agencies, and the public raised multiple issues. Our Draft CCP addresses them. A full description of each alternative is in the EA (see Appendix A). To address these issues, we developed and evaluated the following alternatives, summarized in the table below.

Issue	Alternative A: current management	Alternative B: proposed future management
Landscape-Level Management Issue 1: Ozark Habitat Loss & Fragmentation.	Acquire land from willing sellers or enter into agreements for conservation easements; maintain strong landscape-level partnerships; maintain 4,000 acres of forested habitat; restore 70 acres of agricultural land to forested habitat at Beck Unit; refrain from developing new roads or infrastructure.	Alternative (Alt) A + partner with the FWS southwestern, midwestern, southeastern and mountain-prairie regions to expand acquisition boundaries in the Ozark ecoregion; maintain, conserve, and restore up to 15,000 acres of acquired lands to native forest habitat.
Landscape-Level Management Issue 2: Climate Change.	Monitor baseline data on cave microclimate changes; use energy-efficient heating/cooling system and water filtration system on Looney facility.	Alt A + implement long-term Anabat monitoring stations to monitor climate change impacts to bat species; expand data loggers for climate info; install weather stations; install solar panels on Refuge facilities; sequester carbon by restoring up to 15,000 acres of acquired lands to native forest habitat.
Landscape-Level Management Issue 3: Surface and Groundwater Quality & Quantity.	Survey groundwater recharge areas; acquire land and conservation easements from willing sellers to restore forest and control runoff; partner with adjacent and nearby landowners; sample water quality.	Alt A + partner with U.S. Geological Services (USGS) and local universities to implement a permanent water quality and quantity monitoring program.
Landscape-Level Management Issue 4: White-nose Syndrome (WNS).	Implement actions in WNS National Plan; close caves to the public; partner to monitor for WNS on and off Refuge; take recommended preventative measures in decontamination of staff caving gear; perform public outreach; gain Law Enforcement (LE) support from Sequoyah NWR.	Alt A + coordinate/partner to implement permanent monitoring program to monitor species at risk, track movement and occurrence of WNS, and search for physical signs in Ozark ecoregion; develop a Refuge-specific WNS contingency plan; identify migration corridors; increase LE support; investigate feasibility of installing alarms inside caves.

Issue	Alternative A: current management	Alternative B: proposed future management
Landscape-Level Management Issue 5: Wind Energy Farms.	Monitor baseline data of bird/bat populations affected by wind turbines and determine locations to minimize impacts.	Alt A + identify bat migration corridors; use GIS to delineate high-risk areas; quantify impacts; investigate mitigation measures.
Habitat Management Issue 1: Degradation of Cave, Stream, and Forest Habitat.	Build and repair cave gates on- and off-Refuge; post signs prohibiting entry of caves; maintain confidentiality of cave locations; gain LE support ''on call'' from Sequoyah NWR; partner with landowners; survey and mark boundaries; implement fire management plans for Looney and Sally Bull Hollow Units.	Alt A + increase LE presence; install alarm systems and infrared cameras at caves; search for unknown caves with partners; outreach to landowners.
Habitat Management Issue 2: Lack of Detailed Scientific Cave Habitat Data.	Perform cave bio-inventories; survey bat hibernacula and maternity sites; survey cavefish and cave crayfish; map subterranean extent of caves.	Alt A + partner to develop habitat suitability indexes for cave species; research effects of prescribed burning/thinning on cave habitats and wildlife; implement acoustic monitor program for non-listed species; survey macroinvertebrates and other cave fauna.
Habitat Management Issue 3: Invasive Flora	Remove with handtools, chainsaws, and mow on 10 acres; partner for burns and invasive control; inventory vegetation with Oklahoma State University; (see *Fire Management,* below).	Alt A + work with partners to identify, document, and monitor all plant species occurring on the Refuge; assess changes in vegetation over time; use mechanical treatments and if necessary, use herbicide spot-treatment a maximum of one to three applications per year, March–November (see *Fire Management,* below).
Habitat Management Issue 4: Fire Management	Coordinate response to all wildfires based on ecological, social, and legal consequences of fire; implement Fire Management Plans for Looney and Sally Bull Hollow Units, including prescribed burns of 400 acres/year every 3–5 years.	Alt A + develop a Refuge-wide Fire Management Plan to increase use of prescribed fire to ⅓ of Refuge's total acreage/year every 3–5 years; establish agreements with landowners to increase use of prescribed fire surrounding the Refuge; monitor effects of prescribed fire and midstory thinning on habitats and species.
Wildlife Management Issue 1: Threatened and Endangered (T&E) Species and Species of Concern.	Continue annual bio-inventorying research of cave fauna; monitor surveys of bat populations, activity, guano measurements, and cavefish/crayfish counts; monitor emergence/foraging/migration of bat species using radio telemetry, infrared video, and thermal imaging; partner with universities for genetic research.	Alt A + establish permanent, stationary acoustic monitors in and around caves on all Units; establish permanent acoustic survey program on designated routes; develop a habitat suitability index model for T&E cave species; increase genetic research; install permanent cameras in caves; increase prescribed fires to all Units (see *Fire Management*).
Wildlife Management Issue 2: Migratory and Resident Bird Species.	Conduct bird counts during migration seasons; use prescribed fire on Looney and Sally Bull Hollow Units; enforce limited public use.	Alt A + identify all migratory bird species occurring on or near the Refuge (spring and fall); conduct seasonal nesting studies and MAPS banding of birds monthly for 6 months each year; increase prescribed fires to all Units (see *Fire Management*).
Wildlife Management Issue 3: Resident Non-T&E Species.	Conduct mobile acoustic monitoring once or twice a month from spring through fall from roadways and cave entrances; perform bio-inventories in 2–3 caves every 5 years.	Alt A + establish permanent, stationary acoustic monitors in and around caves on all Units; establish permanent acoustic survey program on designated routes; perform annual count surveys of non-listed cavefish and mark recapture of cave crayfish; survey all wildlife species occurring on Refuge; increase genetic research of cave species; install permanent cameras in caves; increase prescribed fires to all Units (see *Fire Management*).
Wildlife Management Issue 4: Invasive Fauna Species and Pest Management.	No management for invasive fauna species and/or pests.	Partner to identify, document, and monitor all species occurring on the Refuge; conduct a feral hog, feral cat, and hothouse millipede survey; research eradication strategies; if necessary, develop an Integrated Pest Management Plan.
Public Use Management Issue 1: Hunting	No hunting permitted	Develop a Hunt Plan to allow walk-in-only, open-access hunting on the Sally Bull Hollow Unit, adjacent to the State-managed Ozark Plateau Wetlands Management Area (WMA).

Issue	Alternative A: current management	Alternative B: proposed future management
Public Use Management Issue 2: Environmental Education (EE).	Partner to offer place-based EE programs on the Looney Unit and at the Mary & Murray Looney Education & Research Center (MMLERC), by permit only, limited to 10–20 people, 2–3 times per month in spring and fall, 1–2 times per month in summer and 1 per month in winter.	Alt A + increase visitation to 50–100 people per week, 3–4 times per week in spring, summer, and fall and 10–20 people per week, 1–2 times per week in winter; expand programs to include after- and home-school, teacher continuing education, gardening program, tribal-lead; train other FWS and partner agencies in effective EE methods; if necessary, develop a Visitor Services Plan.
Public Use Management Issue 3: Interpretation	Partner to conduct interpretation programs on the Looney Unit and MMLERC, by permit only, for approximately 25 people per month on-site and to 5 to 100s of people per month off-site.	Alt A + offer interpretive programs to include permaculture gardening, showcase Refuge use of sustainable/green technologies; if necessary, develop a Visitor Services Plan.
Public Use Management Issue 4: Wildlife Observation & Photography.	Provide opportunities by permit only on the Looney Unit, in conjunction with interpretive and/or EE programs.	Alt A + allow walk-in access of wildlife observation and photography on Sally Bull Hollow Unit, aside from hunting season; explore additional opportunities on acquired lands; prohibit use in caves; install photography blinds and 3 primitive overlook areas on Looney Unit trails and potentially newly acquired lands.
Public Use Management Issue 5: Wood Harvesting.	Prohibit wood harvesting by the public	Permit wood harvesting by the public of downed-trees as Refuge forest and wildlife management needs dictate.
Public Use Management Issue 6: Public Outreach.	Maintain confidentiality to protect Refuge resources (no pamphlets/fliers available).	Create a flier/brochure to advertise Visitor Services opportunities and update Refuge websites to include contact info; work with volunteers to establish an official Friends group to assist with public outreach.
Cultural/Historical Resources Management Issue 1: Historical Sites.	Keep sites confidential; partner with State Historic Preservation Office (SHPO) to preserve sites.	Alt A + increase LE from Sequoyah NWR to secure known sites; partner to preserve and perform studies on known sites and newly discovered sites.
Cultural/Historical Resources Management Issue 2: Archeological and Paleontological Sites.	Keep sites confidential; partner with SHPO, Sam Noble Museum archeologists, and paleontologists to preserve sites.	Alt A + increase LE from Sequoyah NWR to secure known sites; partner to preserve and survey known sites and newly discovered sites.
Facilities/Infrastructure Management Issue 1: Mary & Murray Looney Education & Research Center (MMLERC).	Operate and maintain MMLERC (1,200 sq. ft.) facility; maintain Americans with Disability Act (ADA) accessibility.	Alt A + renovate roof; insulate basement and attic; renovate cabin exterior; renovate porch; renovate front door to be ADA-accessible; renovate one bathroom to be ADA-accessible; install monitored alarm system; replace plumbing system; replace electrical system; replace propane gas lines; install energy-efficient windows; maintain water filter; install rainwater collection system; build raised garden beds and relandscape with native plants; install solar panels; use energy-efficient heating and cooling system and appliances; install A/V technology; remove small cabin adjacent to MMLERC and replace with a 800 sq. ft. outdoor pavilion studio space and bridge.
Facilities/Infrastructure Management Issue 2: Access Roads.	Maintain a 0.25-mile unpaved and unimproved access road to the MMLERC, with a gate; maintain an unpaved parking area for approximately 10 vehicles; excess parking near the maintenance shop.	Alt A + improve roads and parking areas, including: widen MMLERC access drive/parking area by 2 feet and improve with gravel; improve road with gravel from county road to maintenance shop; improve parking area surfaces with gravel; improve 0.3 miles of gravel road on Beck Unit; improve and/or maintain roads on newly acquired lands, if necessary.

Issue	Alternative A: current management	Alternative B: proposed future management
Facilities/Infrastructure Management Issue 3: Nature Trails and Overlooks.	Utilize and maintain trails around the Refuge, including: deteriorating path from the MMLERC to the pavilion, small path from the parking area to the MMLERC, ¼-mile trail from MMLERC to Spavinaw Creek, ⅛-mile trail from MMLERC to the old garden area at top of hill, 150-yard trail from Guess house to the MMLERC, and ¼-mile trails near the Guess house; no established overlook areas.	Alt A + Establish a 0.25-mile primitive trail to connect the MMLERC trail to maintenance shop trail; build a 2-mile primitive trail around the perimeter of the Looney Unit; repave the 0.1-mile concrete path from the MMLERC cabin to the pavilion; improve the 0.25-mile trail with gravel from the Looney maintenance shop to the MMLERC; improve the 0.1-mile primitive trail with gravel from the parking/camping area on top of the hill down to the MMLERC.
Facilities/Infrastructure Management Issue 4: Public Use Signs and Interpretive Displays.	No public use signs or interpretive signs posted on any Refuge units, except for outside of caves stating that they are closed to the public.	Construct and post a sign for the MMLERC and new HQ site; install directional MMLERC sign at the county road entrance; install signs at all cave entrances to prohibit public entry and also to inform them about White-nose Syndrome (WNS); install limited interpretive signage on Looney Unit.
Facilities/Infrastructure Management Issue 5: Refuge Headquarters (HQ) Site.	No centralized HQ site—each staff member works out of the Oklahoma ES Office in Tulsa, the MMLERC (Refuge), and/or Sequoyah NWR.	Acquire up to 15,000 acres of land and conservation easements from willing sellers within the approved acquisition boundary and utilize an acquired building(s), if appropriate, for new centralized HQ site; or build a new HQ site on centralized acquired site.
Facilities/Infrastructure Management Issue 6: Boundaries.	Maintain and repair 60 miles of Unit boundaries with a total of over 4 miles of fencing and 11 gates.	Alt A + Contract surveyors to survey and mark all un-surveyed/un-marked Unit boundaries on the Refuge; maintain new markers.
Facilities/Infrastructure Management Issue 7: Maintenance Shops and Service Buildings.	Utilize and maintain three maintenance shops: Beck Unit Shop—50 x 30 ft metal building on concrete pad, Looney Unit: 50 x 30 ft metal building on concrete pad, and Guess House Shop.	Alt A + build an additional 50 x 100 ft metal building on concrete pad maintenance shop at new HQ site; construct additional decontamination and storage facility at new HQ, with ventilation building; outfit facilities; construct a fueling station for Refuge vehicles and equipment at new HQ; reconstruct existing pole barn on the Beck Unit.
Facilities/Infrastructure Management Issue 8: Refuge Housing.	Provide Refuge housing for Refuge staff at the Guess House and one bedroom for staff, volunteers, guests, etc. at the MMLERC cabin (Looney Unit); maintain agreement with Leslie Krause.	Alt A + once HQ is established, convert existing Refuge office to a second guest room at the MMLERC; new HQ plan would include kitchen/bath facilities; construct two Recreational Vehicle (RV) pads at the new HQ site; construct RV pad on the Looney Unit; when agreement with Leslie Krause is terminated (donation), renovate Krause residence for Refuge housing.
Administration Management Issue 1: Funding and Staffing.	Receive funding and staffing for operations, infrastructure, and maintenance, determined by Congress and allocated to refuges by the Southwest Regional Office of the U.S. Fish and Wildlife Service; seek additional funding such as applying for grants and working with Non-Government Organizations (NGOs) in order to leverage funds.	Same as Alt A.
Administration Management Issue 2: Volunteers/Friends Program.	No official Friends group established (support from National Speleological Society local chapters); approximately 5,000 to 10,000 volunteer hours total per year.	Alt A + coordinate with unofficial Friends group and/or dedicated volunteer members to encourage formation of official Friends Group; perform outreach to increase part-time, non-resident volunteers to approximately 10,000 to 20,000 volunteer hours per year; educate and train volunteers.

Issue	Alternative A: current management	Alternative B: proposed future management
Administration Management Issue 3: Coordinate Beyond FWS Regional Boundaries to More Effectively Manage Federally Listed Cave Species on a Landscape Level.	No management agreement in place to coordinate across FWS Regional boundaries to manage cave habitat and species.	Coordinate with the State of Arkansas and FWS Region 4 to manage or co-manage Logan Cave NWR as a Unit of Ozark Plateau NWR; coordinate with the State of Missouri and FWS Region 3 to manage or co-manage Cavefish NWR and Pilot Knob NWR as Units of Ozark Plateau NWR; coordinate with the State of Kansas and FWS Region 6 for Ozark Plateau NWR to cooperate management of federally listed Ozark cave species; expand and establish new acquisition areas within the Ozark landscape across multiple State and Regional boundaries.

Public Availability of Documents

In addition to any methods in **ADDRESSES**, you can view or obtain documents at the following locations:

- *Our Web site: http://www.fws.gov/southwest/refuges/Plan/plansinprogress.html.*
- *At the following public libraries:*

Library	Address	Phone number
Delaware County Library	429 South 9th St., Jay, OK 74346	918–253–8521
Stilwell Public Library	5 N 6th St., Stilwell, OK 74960	918–696–7512
Tahlequah Public Library	120 S College Ave., Tahlequah, OK 74464	918–456–2581
Miami Public Library	200 N. Main, Miami, OK 74354	918–542–3064
Stanley Tubbs Memorial Library	101 E Cherokee Ave., Sallisaw, OK 74955	918–596–7897
Central Library	400 Civic Ctr., Tulsa, OK 74103	918–596–7897

Submitting Comments/Issues for Comment

We consider comments substantive if they:

- Question, with reasonable basis, the accuracy of the information in the document;
- Question, with reasonable basis, the adequacy of the environmental assessment (EA);
- Present reasonable alternatives other than those presented in the EA; and/or
- Provide new or additional information relevant to the assessment.

Next Steps

After this comment period ends, we will analyze each comment and address them in an appendix form of the Final CCP along with a finding of no significant impact.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: November 30, 2012.

Joy Nicholopoulos,

Regional Director, Southwest Region.

[FR Doc. 2013–02976 Filed 2–6–13; 11:15 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–ES–2013–N027; FXES11130300000F3–134–FF03E00000]

Endangered and Threatened Species; Permits

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of issuance of permits.

SUMMARY: We, the U.S. Fish and Wildlife Service, have issued the following permits to conduct certain activities with endangered species under the authority of the Endangered Species Act, as amended (Act).

FOR FURTHER INFORMATION CONTACT: Ms. Lisa Mandell, U.S. Fish and Wildlife Service, Ecological Services—Endangered Species, 5600 American Blvd. West, Suite 990, Bloomington, MN 55437–1458; (612) 713–5343 (phone) or *lisa_mandell@fws.gov* (email).

SUPPLEMENTARY INFORMATION: We have issued the following permits in response to recovery permit applications we received under the authority of section 10 of the Act (16 U.S.C. 1531 *et seq.*). Each permit listed below was issued only after we determined that it was applied for in good faith, that granting the permit would not be to the disadvantage of the listed species, and that the terms and conditions of the permit were consistent with purposes and policy set forth in the Act.

Applicant name	Permit No.	Date issued	Date expired
ABR, INC.	224720	4/10/2012	12/31/2013
AHLSTEDT, STEVEN A	113009	12/13/2012	12/31/2014
BAT CALLS IDENTIFICATION, INC.	60958A	2/17/2012	12/31/2013
BAT CONSERVATION AND MANAGEMENT, INC.	212440	4/9/2012	12/31/2012
BENEDICT, RUSSELL A	06820A	5/16/2012	12/31/2013
BERNARDIN-LOCHMUELLER & ASSOCIATES	06845A	4/10/2012	12/31/2013
BHE ENVIRONMENTAL, INC	38789A	5/24/2012	12/31/2012

Applicant name	Permit No.	Date issued	Date expired
BIDART-BOUZAT, MARIA GABRIELA	43555A	2/22/2012	12/31/2013
BISHOP HILL ENERGY LLC	71464A	7/10/2012	3/1/2014
BOYLES, JUSTIN G	82666A	12/17/2012	12/31/2014
BRITZKE, ERIC R	023666	10/25/2012	12/31/2014
BROWN, ROBERT JEFFREY	74592A	8/3/2012	12/31/2014
CARTER, TIMOTHY C	02560A	3/20/2012	12/31/2013
CARVER, BRIAN D	48833A	4/30/2012	12/31/2013
CAYLOR, MEGAN K	71680A	5/29/2012	12/31/2013
CENTER FOR BIODIVERSITY	006012	4/25/2012	12/31/2016
CIVIL AND ENVIRONMENTAL CONSULTANTS, INC.	07358A	4/19/2012	12/31/2013
CLEVELAND METROPARKS	66724A	5/16/2012	12/31/2013
DAVEY RESOURCE GROUP	235639	8/3/2012	12/31/2013
ECOLOGY & ENVIRONMENT, INC.	212427	5/16/2012	12/31/2012
EGRET ENVIRONMENTAL CONSULTING, LLC	77313A	8/3/2012	12/31/2014
EMERY, SARAH MICHELLE	43607A	1/30/2012	12/31/2013
ENVIRONMENTAL SOLUTIONS AND INNOVATIONS, INC.	02373A	5/31/2012	12/31/2013
ENVIROSCIENCE, INC.	130900	3/23/2012	12/31/2013
FERNANDO, DANILO D	77384A	7/30/2012	12/31/2014
FISHMAN, MICHAEL SAMUEL	77310A	10/19/2012	12/31/2014
FOREST PRESERVE DISTRICT OF WILL COUNTY	71720A	6/26/2012	12/31/2013
FOWLER RIDGE WIND FARM	73598A	7/11/2012	6/30/2013
GARVON, JASON MICHAEL	38860A	4/25/2012	12/31/2012
GILMORE, MARY BRIGID	62311A	3/7/2012	12/31/2013
HALE, BENJAMIN T	71827A	7/16/2012	12/31/2013
HOGGARTH, MICHAEL A.	194099	4/19/2012	12/31/2013
ILLINOIS NATURAL HISTORY SURVEY	73584A	8/6/2012	12/31/2015
ILLINOIS NATURAL HISTORY SURVEY	182436	1/4/2012	12/31/2012
ILLINOIS STATE MUSEUM	10891A	4/9/2012	12/31/2014
INDIANA UNIVERSITY-PURDUE UNIVERSITY FT WAYNE	77369A	7/25/2012	12/31/2013
KAPUSINSKI, DOUGLAS J	77530A	10/10/2012	12/31/2014
KLOCEK, ROGER A	71737A	7/11/2012	12/31/2013
LEWIS ENVIRONMENTAL CONSULTING, LLC	181256	4/12/2012	12/31/2013
MAINSTREAM COMMERCIAL DIVERS, INC.	02344A	4/10/2012	12/31/2013
MALACOLOGICAL CONSULTANTS	73128A	7/16/2012	12/31/2013
MALCOSKY, MICHELLE	08603A	6/29/2012	12/31/2013
MCCLANAHAN, ROD DANIEL	06797A	2/16/2012	12/31/2013
MILLER, LEVI D	60999A	3/1/2012	12/31/2013
MISSOURI DEPARTMENT OF CONSERVATION	71730A	11/27/2012	6/30/2020
MISSOURI DEPT OF CONSERVATION	62313A	2/16/2012	12/31/2014
MORGAN, THERESA SYDNEY	02360A	5/29/2012	12/31/2013
MYERS-KINZIE, MELODY LYNN	82665A	10/10/2012	12/31/2014
OHIO DIVISION OF WILDLIFE	65950A	2/16/2012	12/31/2014
PAVLOVIC, NOEL B	77370A	7/30/2012	12/31/2014
PITTSBURGH WILDLIFE & ENVIRONMENTAL, INC.	06801A	5/29/2012	12/31/2013
REDWING ECOLOGICAL SERVICES, INC.	151107	4/12/2012	12/31/2013
SANDERS ENVIRONMENTAL INC	38842A	6/13/2012	12/31/2014
SHAWNEE NATIONAL FOREST	06778A	5/7/2012	12/31/2013
SMITHSONIAN INSTITUTION	06846A	5/18/2012	12/31/2013
SOLUK, DANIEL A	805269	7/23/2012	12/31/2014
ST. LOUIS ZOO	135297	5/15/2012	12/31/2012
STANTEC CONSULTING SERVICES, INC.	15027A	6/13/2012	12/31/2013
STEFFEN, BRADLEY JAMES	71718A	5/29/2012	12/31/2013
THE NATURE CONSERVANCY	838715	3/23/2012	12/31/2015
THE OHIO DEPARTMENT OF TRANSPORTATION	02651A	4/25/2012	12/31/2013
TIMPONE, JOHN CHARLES	120231	8/24/2012	12/31/2014
TOMASI, THOMAS E	195082	12/5/2012	12/31/2014
TRAGUS ENVIRONMENTAL CONSULTING, INC.	105320	3/5/2012	12/31/2012
U.S. ARMY CORPS OF ENGINEERS	02378A	5/14/2012	12/31/2014
U.S. FISH AND WILDLIFE SERVICE	697830	1/1/2012	12/31/2015
U.S. FISH AND WILDLIFE SERVICE	06841A	5/15/2012	11/30/2014
U.S. FISH AND WILDLIFE SERVICE	206778	5/30/2012	12/31/2014
U.S. FOREST SERVICE	217351	2/16/2012	12/31/2013
U.S. GEOLOGICAL SURVEY	10887A	7/17/2012	12/31/2013
UNIVERSITY OF MICHIGAN	71819A	6/1/2012	12/31/2013
UNIVERSITY OF MINNESOTA	62334A	3/29/2012	12/31/2013
U.S. ARMY CORPS OF ENGINEERS	66634A	8/7/2012	12/31/2014
U.S. GEOLOGICAL SURVEY	207526	3/19/2012	3/31/2014
USDA FOREST SERVICE	06809A	12/17/2012	12/31/2014
VANDE KOPPLE, ROBERT J	11035A	6/22/2012	12/31/2013
VESPER ENVIRONMENTAL LLC	74589A	8/3/2012	12/31/2014
WALTERS, BRIANNE LORRAINE	106220	6/14/2012	12/31/2012
WATTERS, GEORGE THOMAS	088720	6/28/2012	12/31/2012
WELCH, ROBERT JOHN	71834A	8/9/2012	12/31/2014
WESTERN ECOSYSTEMS TECHNOLOGY, INC.	234121	4/2/2012	12/31/2013

Applicant name	Permit No.	Date issued	Date expired
WHITBY, MICHAEL D	62297A	3/5/2012	12/31/2013
WHITTLE, JASON BOHDAN	62286A	3/1/2012	12/31/2013
WILDLIFE SPECIALISTS LLC	66727A	5/29/2012	12/31/2013
ZANATTA, DAVID T	71821A	7/18/2012	12/31/2014

Availability of Documents

Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written requires for a copy of such documents to Lisa Mandell (see **FOR FURTHER INFORMATION CONTACT**).

Authority: The authority for this notice is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Lynn Lewis,

Assistant Regional Director, Ecological Services, Midwest Region.

[FR Doc. 2013–02888 Filed 2–7–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMTC 00900.L16100000.DP0000]

Notice of Public Meeting, Eastern Montana Resource Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Public Meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management (BLM) Eastern Montana Resource Advisory Council (RAC) will meet as indicated below.

DATES: The next regular meeting of the Eastern Montana RAC will be held on March 6, 2013 in Miles City, Montana. The meeting will start at 8:00 a.m. and adjourn at approximately 3:30 p.m.

ADDRESSES: When determined, the meeting location will be announced in a news release.

FOR FURTHER INFORMATION CONTACT: Mark Jacobsen, Public Affairs Specialist, BLM Eastern Montana/Dakotas District, 111 Garryowen Road, Miles City, Montana 59301, (406) 233–2831, *mark_jacobsen@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–677–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The 15-member council advises the Secretary of the Interior through the BLM on a variety of planning and management issues associated with public land management in Montana. At these meetings, topics will include: Miles City and Billings Field Office manager updates, subcommittee briefings, work sessions and other issues that the council may raise. All meetings are open to the public and the public may present written comments to the council. Each formal RAC meeting will also have time allocated for hearing public comments. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited. Individuals who plan to attend and need special assistance, such as sign language interpretation, tour transportation or other reasonable accommodations should contact the BLM as provided above.

Dated: January 29, 2013.

Diane M. Friez,

Eastern Montana—Dakotas District Manager.

[FR Doc. 2013–02892 Filed 2–7–13; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLIDC00000.13XL1109AF. L10100000.MU0000.241A0;4500046855]

Notice of Public Meeting, Coeur d'Alene District Resource Advisory Council Meeting; ID

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Public Meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management (BLM) Coeur d'Alene District Resource Advisory Council (RAC) will meet as indicated below.

DATES: March 7, 2013. The RAC meeting will begin at 9:30 a.m. with a half-hour orientation session for new members. The general meeting will begin at 10:00 a.m. and end no later than 3:30 p.m. The public comment period will be held from 1:00 p.m. to 1:30 p.m. The meeting will be held at the Coeur d'Alene BLM District Office located at 3815 Schreiber Way, Coeur d'Alene, Idaho 83815. Meeting proceedings may also be viewed by the public through video conferencing technology at the Cottonwood Field Office located at 1 Butte Drive, Cottonwood, Idaho 83522.

FOR FURTHER INFORMATION CONTACT: Suzanne Endsley, RAC Coordinator, BLM Coeur d'Alene District, 3815 Schreiber Way, Coeur d'Alene, Idaho 83815 or telephone at (208) 769–5004.

SUPPLEMENTARY INFORMATION: The 15-member RAC advises the Secretary of the Interior, through the Bureau of Land Management, on a variety of planning and management issues associated with public land management in Idaho. The agenda will include the following main topics: A presentation regarding the BLM's proposed Sheep Fire Salvage Timber Sale and a presentation by the Clearwater and Nez Perce National Forests regarding a national forest recreation site review to the Recreation RAC Subcommittee. The agenda will also include updates from the Coeur d'Alene and Cottonwood Field Offices. Additional agenda topics or changes to the agenda will be announced in local press releases. More information is available at *http://www.blm.gov/id/st/en/get_involved/resource_advisory/coeur_d_alene_district.html.* All meetings are open to the public. The public may present written comments to the RAC in advance of the meeting or during the scheduled public forum the day of the meeting. Each formal RAC meeting has allocated time for receiving public comments. Depending upon the number of persons wishing to comment and time available, the time for individual oral comments may be limited. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the BLM as provided above.

Dated: January 29, 2013.

Gary D. Cooper,

District Manager.

[FR Doc. 2013–02893 Filed 2–7–13; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–12032; 2200–3200–665]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before December 29, 2012. Pursuant to section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation. Comments may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service,1201 Eye St. NW., 8th floor, Washington, DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by February 25, 2013. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: January 4, 2013.

J. Paul Loether,

Chief, National Register of Historic Places/National Historic Landmarks Program.

IDAHO

Canyon County

Nampa Valley Grange No.131, (Grange Halls in Idaho) 203 5th Ave., S., Nampa, 13000002

MISSOURI

Jackson County

Bayles Addition Historic District, (Lee's Summit, Missouri MPS), Bounded by SW. Jefferson, SW. 3rd, SW. 5th, SW. 4th & SW. Walnut Sts., Lee's Summit, 13000003

Southwest Third and Southwest Madison Historic District, (Lee's Summit, Missouri MPS), 202 through 300 SW. 3rd St., Lee's Summit, 13000004

St. Louis Independent City

Church of the Messiah, 5261 Enright Ave., St. Louis (Independent City), 13000005

NEVADA

Clark County

El Cortez Hotel and Casino, 600 Fremont St., Las Vegas, 13000010

Washoe County

Washoe County Library, 301 S. Center St., Reno, 13000011

NEW HAMPSHIRE

Rockingham County

North Hampton Town Hall, 231 Atlantic Ave., North Hampton, 13000006

North School, 63 Amesbury Rd., Kensington, 13000007

Union Meetinghouse—Universalist Church, 97 Amesbury Rd., Kensington, 13000008

Strafford County

Smith Chapel, 45 Mill Pond Rd., Durham, 13000009

PUERTO RICO

Ceiba Municipality

Ceiba Fire Station, (Fire Stations in Puerto Rico MPS) 226 Lauro Pineiro Ave., Ceiba, 13000012

Ponce Municipality

Casa Vives, 88 Calle Paseo Atocha, Ponce, 13000013

Sabana Grande Municipality

Cementerio Masonico de la Resp. Logia Igualdad Num. 23 de Sabana Grande, (Cemeteries in Puerto Rico, 1804–1920 MPS) PR 121, Sabana Grande, 13000014

Yabucoa Municipality

Yabucoa Fire Station, (Fire Stations in Puerto Rico MPS) Address Restricted, Yabucoa, 13000015

WASHINGTON

Island County

Deception Pass State Park, 41020 WA 20, Oak Harbor, 13000018

King County

Admiral's House, 13th Naval District, 2001 W. Garfield St., Seattle, 13000016

Colman Automotive Building, 401 E. Pine St., Seattle, 13000017

In the interest of preservation a request to shorten the comment period to three days has been made for the following resource:

DISTRICT OF COLUMBIA

District of Columbia

Embassy of Mexico—MacVeagh House, 2829 16th St., NW., Washington, 13000001

[FR Doc. 2013–02915 Filed 2–7–13; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–12009; 2200–3200–665]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before December 22, 2012. Pursuant to section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation. Comments may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St. NW., 8th floor, Washington, DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by February 25, 2013. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: December 20, 2012.

Roger Reed,

Acting Chief, National Register of Historic Places/National Historic Landmarks Program.

FLORIDA

Orange County

Kerouac, Jack, House, 1418 Clouser Ave., Orlando, 12001254

Sarasota County

Warm Mineral Springs Motel, (Sarasota School of Architecture MPS), 12597 S. Tamiami Trail, North Port, 12001255

MISSOURI

Jackson County

Marty, Albert, Building, (Railroad Related Historic Commercial and Industrial Resources in Kansas City, Missouri MPS), 1412–1418 W. 12th St., Kansas City, 12001257

St. Louis Independent City

Lindell Park Subdivision, Bounded by N. Grand Blvd., Natural Bridge, Glasgow & St.

Louis Aves., St. Louis (Independent City), 12001256

NEW YORK

Jefferson County

First Presbyterian Society of Cape Vincent, (Cape Vincent Town and Village MRA), 260 E. Broadway, Cape Vincent, 12001258

Montgomery County

First Methodist Episcopal Church of St. Johnsville, 5 W. Main St., St. Johnsville, 12001259

Schoharie County

Terpenning—Johnson House and Cemetery, 674 Brooker Hollow Rd., Brooker Hollow, 12001260

West Fulton Methodist Church, 849 West Fulton Rd., West Fulton, 12001261

NORTH CAROLINA

Polk County

Tryon Country Club, 393 Country Club Rd., Tryon, 12001262

SOUTH CAROLINA

Pickens County

Hester Store, 1735 Hester Store Rd., Easley, 12001263

York County

Rock Hill Printing and Finishing Company, 400 W. White St., Rock Hill, 12001264

VIRGINIA

Augusta County

Hanger Mill (Boundary Increase), Jct. of VA 801 & US 250, Churchville, 12001265

Fairfax County

Bloomfield, 12000 Leesburg Pike, Herndon, 12001266

Falls Church Independent City

Bancroft, Edwin and Mary Ellen Henderson, House, 307 S. Maple Ave., Falls Church (Independent City), 12001267

Franklin Independent City

Hayden High School, 610–678 Oak St., Franklin (Independent City), 12001268

Norfolk Independent City

Seaboard Air Line Railway Building, 221–229 W. Bute St., Norfolk (Independent City), 12001271

Shenandoah County

Stoner—Keller House and Mill, 2900 Battlefield Rd., Strasburg, 12001269

Spotsylvania County

Lansdowne, 4919 Lansdowne Rd., Fredericksburg, 12001270

Stafford County

Stafford Training School, 1739 Jefferson Davis Hwy., Stafford, 12001272

Virginia Beach Independent City

Green Hill, 1721 Lovetts Pond Ln., Virginia Beach (Independent City), 12001273

Winchester Independent City

Morgan, Daniel, House, 226 Amherst St., Winchester (Independent City), 12001274

WISCONSIN

Winnebago County

Kimberly Point Park Lighthouse, 290 Lake Shore Ave., Neenah, 12001275

[FR Doc. 2013–02913 Filed 2–7–13; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–12070; 2200–3200–665]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before January 5, 2013. Pursuant to section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation. Comments may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St. NW., 8th floor, Washington, DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by February 25, 2013. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: December 20, 2012.

J. Paul Loether,

Chief, National Register of Historic Places/National Historic Landmarks Program.

ARIZONA

Maricopa County

Stephens, C.P., DeSoto Six Motorcars, (Phoenix Commercial MRA), 915 N. Central Ave., Phoenix, 13000019

Tempe Double Butte Cemetery Pioneer Section, 2505 W. Broadway Rd., Tempe, 13000020

ARKANSAS

Pulaski County

North Little Rock Veterans Administration Hospital Historic District, (United States Second Generation Veterans Hospitals MPS), 2200 Fort Roots Dr., North Little Rock, 13000021

DISTRICT OF COLUMBIA

District of Columbia

McMillan Park Reservoir Historic District, Roughly bounded by Hobart Pl., NW., Michigan Ave., NW., 1st, 4th, Bryant & North Capitol Sts., NW., Washington, 13000022

GEORGIA

Chatham County

Savannah Pharmacy and Fonvielle Office Building, 914–918 Martin Luther King, Jr. Blvd., Savannah, 13000023

NEW JERSEY

Somerset County

Vermeule, Dr. John, House, 223 Rock Ave., North Plainfield, 13000024

NEW YORK

Cattaraugus County

Aiken, John J., House, 6805 Poverty Hill Rd., Ellicottville, 13000025

Kings County

Storehouse No. 2, U.S. Navy Fleet Supply Base, 850 3rd Ave., Brooklyn, 13000026

New York County

First Battery Armory, (Army National Guard Armories in New York State MPS), 56 W. 66th St., New York, 13000028

The Bowery Historic District, Chatham Square to Cooper Square, Manhattan, 13000027

Niagara County

Schoellkopf Power Station No. 3 Site, E. Bank of Niagara R., Niagara Falls, 13000029

Oswego County

State Street Methodist Episcopal Church, 357 State St., Fulton, 13000030

Otsego County

Morris Village Historic District, Main, Lake, Broad, Grove & Church, Morris, 13000031

OREGON

Marion County

Ek, Magnus and Emma, House, (Silverton, Oregon, and Its Environs MPS), 729 S. Water St., Silverton, 13000032

[FR Doc. 2013–02912 Filed 2–7–13; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–12128; 2200–3200–665]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before January 12, 2013. Pursuant to section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation. Comments may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service,1201 Eye St. NW., 8th floor, Washington, DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by February 25, 2013. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: January 16, 2013.

J. Paul Loether,

Chief, National Register of Historic Places/ National Historic Landmarks Program.

FLORIDA

Pinellas County

Rothman, Maurice and Thelma, House, 1018 Park St., N., Saint Petersburg, 13000034

IOWA

Winneshiek County

Fort Atkinson Historic District, (Ho-Chunk (Winnebago) Removal to the Neutral Ground MPS), 2nd St. & 8th Ave., Fort Atkinson, 13000036

MASSACHUSETTS

Barnstable County

Bourne High School, 85 Cotuit Rd., Bourne, 13000035

Bournedale Village School, 29 Herring Pond Rd., Bourne, 13000037

MISSOURI

Jackson County

Southwest Market Street Historic District, (Lee's Summit, Missouri MPS), 314 through 418 SW. Market St., Lee's Summit, 13000038

NEW YORK

New York County

Murray Hill Historic District (Boundary Increase), (Murray Hill, New York County, New York MPS), E. 34th, 35th, 36th, 37th, 38th & 39th Sts., Lexington, Madison & Park Aves., Manhattan, 13000039

Women's National Republican Club, 3 W. 51st. St., Manhattan, 13000040

Orleans County

Bacon—Harding Farm, (Cobblestone Architecture of New York State MPS), 3077 Oak Orchard Rd., Gaines, 13000041

SOUTH DAKOTA

Davison County

Mitchell Historic Commercial District (Boundary Increase and Decrease), Roughly bounded by Lawler & Rowley Sts., Railroad & 6th Aves., Mitchell, 13000042

TEXAS

Galveston County

Stringfellow Orchards, 7902 TX 6, Hitchcock, 13000043

VIRGINIA

Alexandria Independent City

Alexandria Union Station, 110 Callahan Dr., Alexandria (Independent City), 13000044

Charlottesville Independent City

Charlottesville Coca-Cola Bottling Works, 722 Preston, Charlottesville (Independent City), 13000045

Prince Edward County

First Baptist Church, 100 S. Main St., Farmville, 13000046

WYOMING

Platte County

Grant, Duncan, Ranch Rural Historic Landscape, (Ranches, Farms, and Homesteads in Wyoming, 1860–1960 MPS), 778 Sybille Creek Rd., Wheatland, 13000047

[FR Doc. 2013–02910 Filed 2–7–13; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

Central Gulf of Mexico Planning Area (CPA) Outer Continental Shelf (OCS) Oil and Gas Lease Sale 227

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Final Notice of Sale.

SUMMARY: On Wednesday, March 20, 2013, BOEM will open and publicly announce bids received for blocks offered in CPA Sale 227, in accordance with the provisions of the OCS Lands Act (OCSLA, 43 U.S.C. 1331–1356, as amended) and the regulations issued thereunder (30 CFR part 556). The CPA 227 Final Notice of Sale (NOS) package (Final NOS Package) contains information essential to potential bidders, and bidders are charged with knowing the contents of the documents contained in that package. The Final NOS Package is available at the address and Web site below.

DATES: Public bid reading for CPA Sale 227 will begin at 9 a.m., Wednesday, March 20, 2013, at the Mercedes-Benz Superdome, 1500 Sugarbowl Drive, New Orleans, Louisiana 70112. The lease sale will be held in the St. Charles Club Room on the second floor (Loge Level). Entry to the Superdome will be on the Poydras Street side of the building through Gate A on the Ground Level; parking will be available at Garage 6. All times referred to in this document are local New Orleans time, unless otherwise specified.

Bid Submission Deadline: BOEM must receive all sealed bids between 8 a.m. and 4 p.m. on normal working days, and from 8 a.m. to the Bid Submission Deadline of 10:00 a.m. on Tuesday, March 19, 2013, the day before the lease sale. For more information on bid submission, see Section VII ''Bidding Instructions'' of this document.

ADDRESSES: Interested parties can obtain a Final NOS Package by contacting the Gulf of Mexico (GOM) Region at: Gulf of Mexico Region Public Information Office, Bureau of Ocean Energy Management, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394, (504) 736–2519 or (800) 200–GULF.

Or by visiting the BOEM Web site: *http://www.boem.gov/About-BOEM/BOEM-Regions/Gulf-of-Mexico-Region/Index.aspx.*

Table of Contents

This Final NOS includes the following sections:

I. Lease Sale Area

Areas Offered for Leasing: In CPA Sale 227, BOEM is offering to lease all blocks and partial blocks listed in the document ''List of Blocks Available for Leasing'' included in the Final NOS Package. All of these blocks are shown on the following leasing maps and Official Protraction Diagrams (OPDs):

Outer Continental Shelf Leasing Maps—Louisiana Map Numbers 1 through 12

(These 30 maps sell for $2.00 each.)

LA1 West Cameron Area (Revised July 1, 2011)
LA1A West Cameron Area, West Addition (Revised February 28, 2007)
LA1B West Cameron Area, South Addition (Revised February 28, 2007)
LA2 East Cameron Area (Revised November 1, 2000)
LA2A East Cameron Area, South Addition (Revised November 1, 2000)
LA3 Vermilion Area (Revised November 1, 2000)
LA3A South Marsh Island Area (Revised November 1, 2000)
LA3B Vermilion Area, South Addition (Revised November 1, 2000)
LA3C South Marsh Island Area, South Addition (Revised November 1, 2000)
LA3D South Marsh Island Area, North Addition (Revised November 1, 2000)
LA4 Eugene Island Area (Revised November 1, 2000)
LA4A Eugene Island Area, South Addition (Revised November 1, 2000)
LA5 Ship Shoal Area (Revised November 1, 2000)
LA5A Ship Shoal Area, South Addition (Revised November 1, 2000)
LA6 South Timbalier Area (Revised November 1, 2000)
LA6A South Timbalier Area, South Addition (Revised November 1, 2000)
LA6B South Pelto Area (Revised November 1, 2000)
LA6C Bay Marchand Area (Revised November 1, 2000)
LA7 Grand Isle Area (Revised November 1, 2000)
LA7A Grand Isle Area, South Addition (Revised February 17, 2004)
LA8 West Delta Area (Revised November 1, 2000)
LA8A West Delta Area, South Addition (Revised November 1, 2000)
LA9 South Pass Area (Revised November 1, 2000)
LA9A South Pass Area, South and East Additions (Revised November 1, 2000)
LA10 Main Pass Area (Revised November 1, 2000)
LA10A Main Pass Area, South and East Additions (Revised November 1, 2000)
LA10B Breton Sound Area (Revised November 1, 2000)
LA11 Chandeleur Area (Revised November 1, 2000)
LA11A Chandeleur Area, East Addition (Revised November 1, 2000)
LA12 Sabine Pass Area (Revised July 1, 2011)

Outer Continental Shelf Official Protraction Diagrams

(These 19 diagrams sell for $2.00 each.)

NG15–02 Garden Banks (Revised February 28, 2007)
NG15–03 Green Canyon (Revised November 1, 2000)
NG15–05 Keathley Canyon (Revised February 28, 2007)
NG15–06 Walker Ridge (Revised November 1, 2000)
NG15–08 Sigsbee Escarpment (Revised February 28, 2007)
NG15–09 Amery Terrace (Revised October 25, 2000)
NG16–01 Atwater Valley (Revised November 1, 2000)
NG16–02 Lloyd Ridge (Revised August 1, 2008)
NG16–04 Lund (Revised November 1, 2000)
NG16–05 Henderson (Revised August 1, 2008)
NG16–07 Lund South (Revised November 1, 2000)
NG16–08 Florida Plain (Revised February 28, 2007)
NH15–12 Ewing Bank (Revised November 1, 2000)
NH16–04 Mobile (Revised July 1, 2011)
NH16–05 Pensacola (Revised February 28, 2007)
NH16–07 Viosca Knoll (Revised November 1, 2000)
NH16–08 Destin Dome (Revised February 28, 2007)
NH16–10 Mississippi Canyon (Revised November 1, 2000)
NH16–11 De Soto Canyon (Revised August 1, 2008)

Please Note: These GOM leasing maps and OPDs are available for free online in .pdf and .gra formats at *http://www.boem.gov/Oil-and-Gas-Energy-Program/Mapping-and-Data/Official-Protraction-Diagrams.aspx.*

For the current status of all CPA leasing maps and OPDs, please refer to 66 FR 28002 (published May 21, 2001), 69 FR 23211 (published April 28, 2004), 72 FR 27590 (published May 16, 2007), 72 FR 35720 (published June 29, 2007), 73 FR 63505 (published October 24, 2008), and 76 FR 54787 (published September 2, 2011).

All blocks are shown on these leasing maps and OPDs. The available Federal acreage of all whole and partial blocks in this lease sale is shown in the document ''List of Blocks Available for Leasing'' included in the Final NOS Package. Some of these blocks may be partially leased or deferred, or transected by administrative lines such as the Federal/state jurisdictional line. A bid on a block must include all of the available Federal acreage of that block. Information on the unleased portions of such blocks is found in the document ''Central Planning Area, Lease Sale 227, March 20, 2013—Unleased Split Blocks and Available Unleased Acreage of Blocks with Aliquots and Irregular Portions Under Lease or Deferred'' included in the Final NOS Package. For additional information, please call Mr. Lenny Coats, Chief of the Mapping and Automation Section, at (504) 736–1457.

Areas Not Offered for Leasing: The following whole and partial blocks are not offered for lease in this sale:

Whole and partial blocks deferred by the Gulf of Mexico Energy Security Act of 2006, Public Law 109–432:

Pensacola (OPD NH 16–05)

Whole Blocks: 751 through 754, 793 through 798, 837 through 842, 881 through 886, 925 through 930, and 969 through 975

Destin Dome (OPD NH 16–08)

Whole Blocks: 1 through 7, 45 through 51, 89 through 96, 133 through 140, 177 through 184, 221 through 228, 265 through 273, 309 through 317, 353 through 361, 397 through 405, 441 through 450, 485 through 494, 529 through 538, 573 through 582, 617 through 627, 661 through 671, 705 through 715, 749 through 759, 793 through 804, 837 through 848, 881 through 892, 925 through 936, and 969 through 981

DeSoto Canyon (OPD NH 16–11)

Whole Blocks: 1 through 15, 45 through 59, and 92 through 102
Partial Blocks: 16, 60, 61, 89 through 91, 103 through 105, and 135 through 147

Henderson (OPD NG 16–05)

Partial Blocks: 114, 158, 202, 246, 290, 334, 335, 378, 379, 422, and 423

Blocks that are adjacent to or beyond the United States Exclusive Economic Zone in the area known as the northern portion of the Eastern Gap:

Lund South (OPD NG 16–07)

Whole Blocks: 128, 129, 169 through 173, 208 through 217, 248 through 261, 293 through 305, and 349

Henderson (OPD NG 16–05)

Whole Blocks: 466, 508 through 510, 551 through 554, 594 through 599, 637 through 643, 679 through 687, 722 through 731, 764 through 775,

807 through 819, 849 through 862, 891 through 905, 933 through 949, and 975 through 992
Partial Blocks: 467, 511, 555, 556, 600, 644, 688, 732, 776, 777, 820, 821, 863, 864, 906, 907, 950, 993, and 994

Florida Plain (OPD NG 16–08)

Whole Blocks: 5 through 24, 46 through 67, 89 through 110, 133 through 154, 177 through 197, 221 through 240, 265 through 283, 309 through 327, and 363 through 370

Whole and partial blocks that lie within the 1.4 nautical mile buffer zone north of the Continental Shelf Boundary between the United States and Mexico:

Amery Terrace (OPD NG 15–09)

Whole Blocks: 280, 281, 318 through 320, and 355 through 359
Partial Blocks: 235 through 238, 273 through 279, and 309 through 317

Sigsbee Escarpment (OPD NG 15–08)

Whole Blocks: 239, 284, and 331 through 341
Partial Blocks: 151, 195, 196, 240, 241, 285 through 298, and 342 through 349

Blocks that are deferred until measures to ensure the safety of planned decommissioning operations are completed:

Green Canyon (OPD NG15–03) Block 20

Please Note: Bids on Blocks near the U.S.-Mexico Maritime and Continental Shelf Boundary.

The following definitions apply to this section:

''Agreement'' refers to the agreement between the United Mexican States and the United States of America that addresses identification and unitization of transboundary hydrocarbon reservoirs, allocation of production, inspections, safety, and environmental protection. A copy of the Agreement can be found at h*ttp://www.boem.gov/BOEM-Newsroom/Library/Boundaries-Mexico.aspx.*

''Boundary Area'' means an area comprised of any and all blocks in the CPA that are located or partially located within three statute miles of the maritime and continental shelf boundary with Mexico, as that maritime boundary is delimited in the November 24, 1970 Treaty to Resolve Pending Boundary Differences and Maintain the Rio Grande and Colorado River as the International Boundary; the May 4, 1978 Treaty on Maritime Boundaries between the United Mexican States and the United States of America; and the June 9, 2000 Treaty on the Continental Shelf between the Government of the United Mexican States and the Government of the United States of America.

The Agreement was signed on February 20, 2012, but has not yet entered into force. Bids submitted on any available block in the ''Boundary Area'' (as defined previously) may be segregated from bids submitted on blocks outside the Boundary Area. Bids submitted on available blocks outside the Boundary Area will be opened on the date scheduled for sale. Bids submitted on available blocks in the Boundary Area may not be opened on the date scheduled for the sale, but may be opened at a later date. Within 30 days after the approval of the Agreement such that its terms to enter into force, or by September 30, 2013, whichever occurs first, the Secretary of the Interior will determine whether it is in the best interest of the United States either to open bids for available Boundary Area blocks or to return the bids unopened. In the event the Secretary decides to open bids on available blocks in the Boundary Area, BOEM will notify such bidders at least 30 days prior to opening such bids, and will describe the terms of the Agreement under which leases in the Boundary Area will be issued as applicable. Bidders on these blocks may withdraw their bids at any time after such notice up until 10 a.m. of the day before bid opening. If BOEM does not give notice within 30 days of approval of the Agreement as described above, or by September 30, 2013, whichever comes first, BOEM will return the bids unopened. This timing will allow potential bidders to make decisions regarding the next annual CPA lease sale (anticipated in 2014), which may also offer blocks in this area. BOEM currently anticipates that blocks in the Boundary Area that are not awarded as a result of CPA Sale 227 would be reoffered in the next CPA lease sale. BOEM reserves the right to return these bids at any time. BOEM will not disclose which blocks received bids or the names of bidders in this area unless and until the bids are opened.

The following whole and partial blocks comprise the entire Boundary Area (not all of which are available under CPA Sale 227):

Sigsbee Escarpment—151, 152, 195, 196, 197, 239, 240, 241, 242, 243, 284, 285, 286, 287, 288*, 289*, 290*, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340, 341, 342, 343, 344, 345, 346, 347, 348, 349

Amery Terrace—118, 119, 120, 121, 122, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 210, 211, 212, 213, 214, 215, 216, 217, 218, 219, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 265, 266, 267, 271, 272, 273, 274, 275, 276, 277, 278, 279, 280, 281, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 355, 356, 357, 358, 359

Lund South—133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 293, 294, 295, 296

* Leased.

II. Statutes and Regulations

Each lease is issued pursuant to OCSLA, regulations promulgated pursuant thereto, other applicable statutes and regulations in existence upon the effective date of the lease, and those applicable statutes enacted (including amendments to OCSLA or other statutes) and regulations promulgated thereafter, except to the extent they explicitly conflict with an express provision of the lease. Amendments to existing statutes and regulations, including but not limited to OCSLA, as well as the enactment of new statutes and promulgation of new regulations that do not explicitly conflict with an express provision of the lease, will apply to leases issued as a result of this sale. Moreover, the lessee expressly bears the risk that such new statutes and regulations (i.e., those that do not explicitly conflict with an express provision of the lease) may increase or decrease the lessee's obligation under the lease.

III. Lease Terms and Economic Conditions

Lease Terms

OCS Lease Form

BOEM will use Form BOEM–2005 (October 2011) to convey leases resulting from this sale. This lease form may be viewed on the BOEM Web site at *http://www.boem.gov/About-BOEM/Procurement-Business-Opportunities/BOEM-OCS-Operation-Forms/BOEM-2005.aspx.* The lease form will be amended to conform with the specific terms, conditions, and stipulations applicable to the individual lease.

Initial Periods

Initial periods are summarized in the following table:

Water depth in meters	Initial periods
0 to < 400	Standard initial period is 5 years; the lessee may earn an additional 3 years (i.e., for an 8-year extended initial period), if a well is spudded targeting hydrocarbons below 25,000 feet True Vertical Depth Subsea (TVD SS) during the first 5 years of the lease.
400 to < 800	Standard initial period is 5 years; the lessee will earn an additional 3 years (i.e., for an 8-year extended initial period), if a well is spudded during the first 5 years of the lease.
800 to < 1,600	Standard initial period is 7 years; the lessee will earn an additional 3 years (i.e., for a 10-year extended initial period), if a well is spudded during the first 7 years of the lease.
1,600 +	10 years.

(1) The standard initial period for a lease in water depths of less than 400 meters issued from this sale is 5 years. If the lessee spuds a well targeting hydrocarbons below 25,000 feet TVD SS within the first 5 years of the lease, then the lessee may earn an additional 3 years, for an 8-year extended initial period. The lessee will earn the 8-year extended initial period in cases where the well is drilled to a target below 25,000 feet TVD SS, or the lessee may earn the 8-year extended initial period in cases where the well targets, but does not reach, a depth below 25,000 feet TVD SS due to mechanical or safety reasons, where sufficient evidence is provided. In order to earn the 8-year extended initial period, the lessee is required to submit a letter to the Bureau of Safety and Environmental Enforcement (BSEE) GOM Regional Supervisor for Production and Development (RSPD) within 30 days after completion of the drilling operation. The letter must include: (1) The well number; (2) spud date; (3) information demonstrating a target below 25,000 feet TVD SS and whether that target was reached; and (4) if applicable, any safety, mechanical, or other problems encountered that prevented the well from reaching a depth below 25,000 feet TVD SS. The RSPD must concur in writing that the conditions have been met in order for the lessee to earn the 8-year extended initial period. The RSPD will provide a written response within 30 days of receipt of the lessee's letter.

A lessee who earns an 8-year extended initial period by spudding a well with a hydrocarbon target below 25,000 feet TVD SS during the first 5 years of the lease, confirmed by the RSPD, will not be eligible for a suspension for that same period under the regulations at 30 CFR 250.175 because the lease is not at risk of expiring.

(2) The standard initial period for a lease in water depths of 400 meters to less than 800 meters issued from this sale is 5 years. The lessee will earn an additional 3 years, for an 8-year extended initial period, if the lessee spuds a well within the first 5 years of the lease.

In order to earn the 8-year extended initial period, the lessee is required to submit to the appropriate BSEE District Manager, within 30 days after spudding a well, a letter providing the well number and spud date, and requesting concurrence that the lessee has earned the 8-year extended initial period. The BSEE District Manager will review the request and make a written determination within 30 days of receipt of the request. The BSEE District Manager must concur in writing that the conditions have been met by the lessee to earn the 8-year extended initial period.

(3) The standard initial period for a lease in water depths of 800 meters to less than 1,600 meters issued from this sale will be 7 years. The lessee will earn an additional 3 years, for a 10-year extended initial period, if the lessee spuds a well within the first 7 years of the lease.

In order to earn the 10-year extended initial period, the lessee is required to submit to the appropriate BSEE District Manager, within 30 days after spudding a well, a letter providing the well number and spud date, and requesting concurrence that the lessee earned the 10-year extended initial period. The BSEE District Manager will review the request and make a written determination within 30 days of receipt of the request. The BSEE District Manager must concur in writing that the conditions have been met by the lessee to earn the 10-year extended initial period.

(4) The standard initial period for a lease in water depths of 1,600 meters or greater issued from this sale will be 10 years.

Economic Conditions

Minimum Bonus Bid Amounts

- $25.00 per acre or fraction thereof for blocks in water depths of less than 400 meters.
- $100.00 per acre or fraction thereof for blocks in water depths of 400 meters or deeper.

BOEM will not accept a bonus bid unless it provides for a cash bonus in the amount equal to, or exceeding, the specified minimum bid of $25.00 per acre or fraction thereof for blocks in water depths of less than 400 meters, and $100.00 per acre or fraction thereof for blocks in water depths of 400 meters or deeper.

Rental Rates

Annual rental rates are summarized in the following table:

RENTAL RATES PER ACRE OR FRACTION THEREOF

Water depth in meters	Years 1–5	Years 6, 7 & 8+
0 to < 200	$7.00	$14.00, $21.00 & $28.00
200 to < 400	11.00	$22.00, $33.00 & $44.00
400 +	11.00	$16.00

Escalating Rental Rates for Leases With an 8-Year Extended Initial Period in Water Depths of Less Than 400 Meters

Any lease in water depths less than 400 meters that earns an 8-year extended initial period will pay an escalating rental rate as shown above. The rental rates after the fifth year for blocks in less than 400 meters will become fixed and no longer escalate if another well is spudded targeting hydrocarbons below 25,000 feet TVD SS after the fifth year of the lease, and BSEE concurs that such a well has been spudded. In this case, the rental rate will become fixed at the rental rate in effect during the lease year in which the additional well was spudded.

Royalty Rate

- 18.75 percent.

Minimum Royalty Rate

- $7.00 per acre or fraction thereof per year for blocks in water depths of less than 200 meters.
- $11.00 per acre or fraction thereof per year for blocks in water depths of 200 meters or deeper.

Royalty Suspension Provisions

Leases with royalty suspension volumes (RSVs) are authorized under existing BSEE regulations at 30 CFR part 203 and BOEM regulations at 30 CFR part 560.

Deep and Ultra-Deep Gas Royalty Suspensions

A lease issued as a result of this sale may be eligible for RSV incentives for deep and ultra-deep wells pursuant to 30 CFR part 203, implementing requirements of the Energy Policy Act of 2005. These RSV incentives are conditioned upon applicable price thresholds.

- Certain wells on leases in 0 to less than 400 meters of water depth completed to a drilling depth of 20,000 feet TVD SS or deeper may receive an RSV of 35 billion cubic feet of natural gas.
- Certain wells on leases in 200 to less than 400 meters of water depth completed to a drilling depth from 15,000 to 20,000 feet TVD SS that begin production before May 3, 2013, may receive smaller RSV incentives.

IV. Lease Stipulations

One or more of the following stipulations will be applied to leases resulting from this sale as applicable. The detailed text of these stipulations is contained in the Lease Stipulations section of the Final NOS Package.

(1) Topographic Features
(2) Live Bottoms
(3) Military Areas
(4) Evacuation
(5) Coordination
(6) Blocks South of Baldwin County, Alabama
(7) Law of the Sea Convention Royalty Payment
(8) Protected Species
(9) Below Seabed Operations
(10) Agreement between the United States of America and the United Mexican States Concerning Transboundary Hydrocarbon Reservoirs in the Gulf of Mexico

V. Information to Lessees

The ''Information to Lessees'' (ITL) clauses provide detailed information on certain issues pertaining to this oil and gas lease sale. The detailed text of these ITL clauses is contained in the ''Information to Lessees'' section of the Final NOS Package:

(1) Navigation Safety
(2) Ordnance Disposal Areas
(3) Communications Towers
(4) Existing and Proposed Artificial Reefs/Rigs to Reefs
(5) Lightering Zones
(6) Indicated Hydrocarbons List
(7) Military Areas
(8) Safety Zones for Certain Production Facilities
(9) Bureau of Safety and Environmental Enforcement (BSEE) Inspection and Enforcement of Certain Coast Guard Regulations
(10) Ocean Dredged Material Disposal Sites
(11) Potential Sand Dredging Activities
(12) Below Seabed Operations
(13) Commercial Waste Disposal Areas
(14) Air Quality Permits
(15) Notice of Arrival on the Outer Continental Shelf
(16) Bids on Blocks near U.S.-Mexico Maritime and Continental Shelf Boundary

VI. Maps

The following maps are included in the Final NOS Package; they also may be found on the BOEM Web site at *http://www.boem.gov/sale-227/.*

Lease Terms and Economic Conditions Map

The lease terms and economic conditions and the blocks to which these terms and conditions apply are shown on the map ''Final, Central Planning Area, Lease Sale 227, March 20, 2013, Lease Terms and Economic Conditions'' included in the Final NOS Package.

Stipulations and Deferred Blocks Map

The blocks on which one or more lease stipulations apply are shown on the map, ''Final, Central Planning Area, Lease Sale 227, March 20, 2013, Stipulations and Deferred Blocks Map,'' included in the Final NOS Package.

VII. Bidding Instructions

Instructions on how to submit a bid, secure payment of the advance bonus bid deposit (if applicable), and what information must be included with the bid are as follows:

Bid Form

For each block bid upon, a separate sealed bid shall be submitted in a sealed envelope (as described below) and must include the following:

- Total amount of the bid in whole dollars only;
- Sale number;
- Sale date;
- Each bidder's exact name;
- Each bidder's proportionate interest, stated as a percentage, using a maximum of five decimal places (e.g., 33.33333%);
- Typed name and title, and signature of each bidder's authorized officer;
- Each bidder's GOM company number;
- Map name and number or OPD name and number;
- Block number; and
- Statement acknowledging that the bidder(s) understand that this bid legally binds the bidder(s) to comply with all applicable regulations including payment of one-fifth of the bonus bid amount on all apparent high bids.

The information required on the bid(s) is specified in the document ''Bid Form'' contained in the Final NOS Package. A blank bid form has been provided therein for convenience and may be copied and completed with the necessary information described above.

Bid Envelope

Each bid must be submitted in a separate sealed envelope labeled as follows:

- ''Sealed Bid for Oil and Gas Lease Sale 227, not to be opened until 9 a.m. Wednesday, March 20, 2013'' or if the bid is on a block in the U.S.-Mexico Maritime Boundary Area, ''Sealed Bid for Oil and Gas Lease Sale 227 U.S.-Mexico Maritime Boundary Bid, not to be opened until Transboundary Agreement is approved by Congress or September 30, 2013;''
- Map name and number or OPD name and number;
- Block number for block bid upon; and
- The exact name and GOM company number of the submitting bidder only.

The Final NOS Package includes a sample bid envelope for reference.

Mailed Bids

If bids are mailed, please address the envelope containing the sealed bid envelope(s) as follows:

Attention: Leasing and Financial Responsibility Section, BOEM Gulf of Mexico Region, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394. Contains Sealed Bids for CPA Oil and Gas Lease Sale 227. Please Deliver to Ms. Cindy Thibodeaux or Ms. Kasey Couture, 2nd Floor, Immediately.

Please Note: Bidders mailing bid(s) are advised to call Ms. Cindy Thibodeaux at (504) 736–2809, or Ms. Kasey Couture at (504) 736–2909, immediately after putting their bid(s) in the mail. If BOEM receives bids later than the Bid Submission Deadline, the BOEM Regional Director (BOEM RD) will return those bids unopened to bidders. Should an unexpected event, such as flooding or travel restrictions be significantly disruptive to bid submission, BOEM may extend the Bid Submission Deadline. Bidders may call (504) 736–0557 or access the BOEM Gulf of Mexico Regional Web site at *http://www.boem.gov/About-BOEM/BOEM-Regions/Gulf-of-Mexico-Region/Index.aspx* for information about the possible extension of the Bid Submission Deadline due to such an event.

Advance Bonus Bid Deposit Guarantee

Bidders that are not currently an OCS oil and gas lease record title holder or designated operator or those that ever have defaulted on a one-fifth bonus bid deposit, by Electronic Funds Transfer (EFT) or otherwise, must guarantee (secure) the payment of the one-fifth bonus bid deposit prior to bid submission using one of the following four methods:

- Provide a third-party guarantee;
- Amend areawide development bond via bond rider;
- Provide a letter of credit; or
- Provide a lump sum payment in advance via EFT.

For more information on EFT procedures, see ''The Lease Sale'' Section X of this document.

Affirmative Action

BOEM requires that, prior to bidding, the bidder file Equal Opportunity Affirmative Action Representation Form BOEM–2032 (October 2011) and Equal Opportunity Compliance Report Certification Form BOEM–2033 (October 2011) in the BOEM Gulf of Mexico Region Adjudication Section. This certification is required by 41 CFR part 60 and Executive Order No. 11246, issued September 24, 1965, as amended by Executive Order No. 11375, issued October 13, 1967. Please note that both forms are required to be on file for the bidder(s) in the GOM Region Adjudication Section prior to the execution of any lease contract.

Geophysical Data and Information Statement (GDIS)

Pursuant to 30 CFR 551.12, BOEM has a right to access geophysical data and information collected under a permit in the OCS. Every bidder submitting a bid on a block in CPA Sale 227, or participating as a joint bidder in such a bid, must submit at the time of bid submission a GDIS in a separate and sealed envelope, identifying all proprietary data; reprocessed speculative data and/or any Controlled Source Electromagnetic surveys, Amplitude Versus Offset, Gravity or Magnetic data; or other information used as part of the decision to bid or participate in a bid on the block.

Please Note: A bidder must submit the GDIS even if its joint bidder or bidders on a specific block also have submitted a GDIS. Any speculative data that has been reprocessed externally or ''in-house'' is considered proprietary due to the proprietary processing and is no longer considered to be speculative. The GDIS should clearly state who did the reprocessing (e.g., external company name or ''in-house''). In addition, the GDIS should clearly identify the data type (e.g., 2–D, 3–D, or 4–D, pre-stack or post-stack, and time or depth); areal extent (i.e., number of line miles for 2–D or number of blocks for 3–D) and migration algorithm (e.g., Kirchhoff Migration, Wave Equation Migration, Reverse Migration, Reverse Time Migration) of the data; velocity models used; and other requested metadata. The statement also must include the name; phone number, and full address of a contact person and an alternate who are both *knowledgeable* about the information and data listed and *available* for 30 days post-sale; the processing company; date processing was completed; owner of the original data set (who initially acquired the data); and original data survey name and permit number. Seismic survey information also should include the computer storage size, to the nearest megabyte, of each seismic data set and velocity volume used to evaluate the lease block in question. This will be used in estimating the reproduction costs for each data set during the requisition process prior to requesting data. BOEM reserves the right to query alternate data sets, to quality check, and to compare the listed and alternative data sets to determine which data set most closely meets the needs of the fair market value determination process.

The GDIS must also include entries for all blocks bid upon that did not use proprietary or reprocessed pre- or post-stack geophysical data and information as part of the decision to bid or to participate as a joint bidder in the bid. The GDIS must be submitted even if no proprietary geophysical data and information were used in bid preparation for the block. In the event a person (as defined at 30 CFR 556.43) supplies any type of data to BOEM, that person must meet the following requirements to qualify for reimbursement:

(1) Persons must be registered with the System for Award Management (SAM), formerly known as the Central Contractor Registration (CCR). Your CCR username will not work in SAM. A new SAM User Account is needed to register or update your entity's records. The Web site for registering is *https://www.sam.gov*.

(2) Persons must be enrolled in the Department of Treasury's Internet Payment Platform (IPP) for electronic invoicing. The person must enroll at the IPP (*https://www.ipp.gov/*) if it has not already done so. Access then will be granted to use IPP for submitting requests for payment. When a request for payment is submitted, it must include the assigned Purchase Order Number on the request.

(3) Persons must have a current On-line Representations and Certifications Application at *https://www.sam.gov.*

Please Note: The GDIS Information Table can be submitted digitally as an Excel spreadsheet on a CD or DVD. If you have any questions, please contact Ms. Dee Smith at (504) 736–2706, or Mr. John Johnson at (504) 736–2455.

Telephone Numbers/Addresses of Bidders

BOEM requests that bidders provide this information in the suggested format prior to or at the time of bid submission. This form shall not be enclosed inside the sealed bid envelope.

Additional Documentation

BOEM may require bidders to submit other documents in accordance with 30 CFR 556.46.

VIII. Bidding Rules and Restrictions

Restricted Joint Bidders

BOEM published in the **Federal Register** a List of Restricted Joint Bidders, which applies to this lease sale, at 77 FR 64826 on October 23, 2012. Please refer to joint bidding provisions at 30 CFR 556.41 for additional restrictions.

Authorized Signatures

All bidders must execute all documents in conformance with signatory authorizations on file in the BOEM Gulf of Mexico Region Adjudication Office. Designated signatories must be authorized to bind their respective legal business entity (e.g., a corporation, partnership, or LLC) and must have an incumbency

certificate setting forth the authorized signatories on file with the BOEM Gulf of Mexico Region Adjudication Office. Bidders submitting joint bids must include on the bid form the proportionate interest of each participating bidder, stated as a percentage, using a maximum of five decimal places (e.g., 33.33333 percent) with total interest equaling 100 percent.

Bidders are advised that BOEM considers the signed bid to be a legally binding obligation on the part of the bidder(s) to comply with all applicable regulations, including payment of one-fifth of the bonus bid on all high bids. A statement to this effect must be included on each bid form (see the document ''Bid Form'' contained in the Final NOS Package).

Unlawful Combination or Intimidation

BOEM warns bidders against violation of 18 U.S.C. 1860, prohibiting unlawful combination or intimidation of bidders.

Bid Withdrawal

Bids may be withdrawn only by written request delivered to BOEM prior to the Bid Submission Deadline. The withdrawal request must be on company letterhead and must contain the bidder's name, its company number, the map name/number, and the block number(s) of the bid(s) to be withdrawn. The request must be in conformance with signatory authorizations on file in the BOEM Gulf of Mexico Region Adjudication Office. Signatories must be authorized to bind their respective legal business entities (e.g., a corporation, partnership, or LLC) and must have: (1) An incumbency certificate and/or (2) specific power of attorney setting forth express authority to act on the business entity's behalf for purposes of bidding and lease execution under OCSLA. The name and title of the signatory must be typed under the signature block on the withdrawal letter. Upon the BOEM Regional Director's (RD), or his designee's, approval of such requests, he or she will indicate their approval by signing and dating the withdrawal request.

Bid Rounding

The bonus bid amount must be stated in whole dollars. If the acreage of a block contains a decimal figure, then prior to calculating the minimum bonus bid, bidders must round up to the next whole acre. The appropriate minimum rate per acre is then applied to the whole (rounded up) acreage. If this calculation results in a fractional dollar amount, bidders must round up to the next whole dollar amount. The bonus bid amount must be greater than or equal to the minimum bonus bid. Minimum bonus bid calculations, including all rounding, for all blocks are shown in the document ''List of Blocks Available for Leasing'' included in the Final NOS Package.

IX. Forms

The Final NOS Package includes forms, samples, and the preferred format for the following items. Bidders are strongly encouraged to use these formats; should bidders use another format, they are responsible for including all the information specified for each item in this Final NOS Package.

(1) Bid Form
(2) Sample Completed Bid
(3) Sample Bid Envelope
(4) Sample Bid Mailing Envelope
(5) Telephone Numbers/Addresses of Bidders Form
(6) GDIS Form
(7) GDIS Envelope Form

X. The Lease Sale

Bid Opening and Reading

Sealed bids received in response to the Final NOS will be opened at the place, date and hour specified in this Final NOS. The opening of the bids is for the sole purpose of publicly announcing and recording the bids received; no bids will be accepted or rejected at that time.

Bonus Bid Deposit for Apparent High Bids

Each bidder submitting an apparent high bid must submit a bonus bid deposit to the U.S. Department of the Interior's Office of Natural Resources Revenue (ONRR) equal to one-fifth of the bonus bid amount for each such bid. A copy of the notification of the high bidder's one-fifth bonus liability may be obtained at the EFT Area outside the Bid Reading Room on the day of the bid opening, or it may be obtained on the BOEM Web site at *http://www.boem.gov/Sale-227/* under the heading ''Notification of EFT 1/5 Bonus Liability.'' All payments must be deposited electronically into an interest-bearing account in the U.S. Treasury by 11 a.m. Eastern Time the day following bid reading (no exceptions). Account information is provided in the ''Instructions for Making Electronic Funds Transfer Bonus Payments'' found on the BOEM Web site identified above.

BOEM requires bidders to use EFT procedures for payment of one-fifth bonus bid deposits for CPA Sale 227, following the detailed instructions contained on the Payment Information Web page that may be found on the ONRR Web site at *http://www.onrr.gov/FM/PayInfo.htm.* Acceptance of a deposit does not constitute and shall not be construed as acceptance of any bid on behalf of the United States.

Withdrawal of Blocks

The United States reserves the right to withdraw any block from this lease sale prior to issuance of a written acceptance of a bid for the block.

Acceptance, Rejection, or Return of Bids

The United States reserves the right to reject any and all bids. No bid will be accepted, and no lease for any block will be awarded to any bidder, unless the bidder has complied with all requirements of this Final NOS, including those set forth in the documents contained in the Final NOS Package and applicable regulations; the bid is the highest valid bid; and the amount of the bid has been determined to be adequate by the authorized officer. Any bid submitted that does not conform to the requirements of this Final NOS and Final NOS Package, OCSLA, or other applicable statute or regulation may be rejected and returned to the bidder. The U.S. Department of Justice and Federal Trade Commission will review the results of the lease sale prior to the acceptance of bids and issuance of leases for anti-trust issues. To ensure that the Government receives a fair return for the conveyance of leases from this sale, high bids will be evaluated in accordance with BOEM's bid adequacy procedures. A copy of current procedures, ''Modifications to the Bid Adequacy Procedures'' at 64 FR 37560 on July 12, 1999, can be obtained from the BOEM Gulf of Mexico Region Public Information Office, or via the BOEM Gulf of Mexico Region Web site at *http://www.gomr.mms.gov/homepg/lsesale/bidadeq.html.*

Lease Award

BOEM requires each bidder awarded a lease to: (1) Execute all copies of the lease (Form BOEM–2005 (October 2011), as amended), (2) pay by EFT the balance of the bonus bid amount and the first year's rental for each lease issued in accordance with the requirements of 30 CFR 218.155 and 556.47(f); and (3) satisfy the bonding requirements of 30 CFR part 556, subpart I, as amended. ONRR requests that only one transaction be used for payment of the four-fifths bonus bid amount and the first year's rental.

XI. Delay of Sale

The BOEM RD in the Gulf of Mexico Region has the discretion to change any date, time, and/or location specified in the Final NOS Package in case of a *force*

majeure event that the BOEM RD deems may interfere with the carrying out of a fair and proper lease sale process. Such events may include, but are not limited to, natural disasters (e.g., earthquakes, hurricanes, and floods), wars, riots, acts of terrorism, fire, strikes, civil disorder, or other events of a similar nature. In case of such events, bidders should call (504) 736–0557, or access the BOEM Web site at *http://www.boem.gov* for information about any changes.

Dated: January 28, 2013.

Tommy P. Beaudreau,

Director, Bureau of Ocean Energy Management.

[FR Doc. 2013–02701 Filed 2–7–13; 8:45 am]

BILLING CODE 4310–MR–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–857]

Certain Reduced Folate Nutraceutical Products and L-Methylfolate Raw Ingredients Used Therein; Commission Determination Not To Review an Initial Determination Granting Complainants' Unopposed Motion To Correct the Title of Complainants' Unopposed Motion To Amend the Complaint and Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (''ID'') (Order No. 5) of the administrative law judge (''ALJ'') granting complainants' unopposed motion to correct the title of complainants' unopposed motion to amend the complaint and notice of investigation in the above-captioned investigation.

FOR FURTHER INFORMATION CONTACT: James A. Worth, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–3065. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on October 16, 2012, based on a complaint filed on September 10, 2012, on behalf of South Alabama Medical Science Foundation of Mobile, Alabama; Merck & Cie of Altdorf, Switzerland; and Pamlab LLC of Covington, Louisiana (collectively, ''the complainants''). 77 FR 63336 (October 16, 2012). The complaint alleged violations of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, by reason of infringement of one or more of claims 37, 39, 40, 47, 66, 67, 73, 76,78–81, 83, 84, 86–89, 91, 92, 94–97, 99, 100, 110, 111, 113, 117, and 121 of U.S. Patent No. 5,997,915; claims 22, 26, and 32–38 of U.S. Patent No. 6,673,381; claims l, 4–6, and 15 of U.S. Patent No. 7,172,778; and claims 1–3, 5, 6, 8, 9, 11–15, and 19–22 of U.S. Patent No. 6,011,040. The Commission's notice of investigation named as respondents Gnosis SpA of Desio, Italy; Gnosis Bioresearch SA of Sant'Antonino, Switzerland; Gnosis USA Inc. of Doylestown, Pennsylvania; and Macoven Pharmaceuticals LLC of Magnolia, Texas.

On November 14, 2012, the complainants filed an unopposed motion for leave to amend the complaint and notice of investigation, *inter alia,* to add a new respondent. The title of the motion identified the new respondent as Viva Pharmaceuticals LLC, while the body of the motion identified the new respondent as Viva Pharmaceuticals Inc. On November 15, 2012, the ALJ issued an ID, granting the motion to amend the complaint and notice of investigation, *inter alia,* to add Viva Pharmaceuticals LLC as a new respondent. On December 13, 2012, the Commission issued notice of its determination not to review the ID.

On January 8, 2013, the complainants filed an unopposed motion to correct the title of its motion to amend the complaint and notice of investigation such that the respondent is identified as Viva Pharmaceuticals Inc. rather than Viva Pharmaceuticals LLC. On January 14, 2013 ALJ issued the subject ID (Order No. 5), granting the motion for good cause shown. No petitions for review were filed.

Having considered the ID and the relevant portions of the record, the Commission has determined not to review the subject ID. The complaint and notice of investigation are therefore corrected to identify the new respondent as Viva Pharmaceuticals Inc.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of section 210.42(h) of the Commission's Rules of Practice and Procedure (19 CFR 210.42(h)).

Issued: February 4, 2013.

By order of the Commission.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2013–02818 Filed 2–7–13; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–13–007]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission

TIME AND DATE: February 15, 2013 at 11:00 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

Matters To Be Considered

1. Agendas for future meetings: none.

2. Minutes.

3. Ratification List.

4. Vote in Inv. Nos. 701–TA–350 and 731–TA–616 and 618 (Third Review) (Corrosion-Resistant Carbon Steel Flat Products from Germany and Korea). The Commission is currently scheduled to transmit its determinations and Commissioners' opinions to the Secretary of Commerce on or before March 5, 2013.

5. Outstanding action jackets: none.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

Issued: February 6, 2013.

By order of the Commission.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2013–02965 Filed 2–6–13; 11:15 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1105–NEW]

Agency Information Collection Activities; Proposed Collection; Comments Requested: Claims of U.S. Nationals for Compensation for Serious Personal Injuries Against the Government of Iraq and Referred to the Foreign Claims Settlement Commission by the Department of State Legal Adviser

ACTION: 30-day notice.

The Foreign Claims Settlement Commission (Commission), an independent agency organized within the Department of Justice, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 77, Number 236, pages 73051–73052 on December 7, 2012, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment March 11, 2013. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395–5806. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* New collection.

(2) *The title of the form/collection:* Claims of U.S. Nationals Against Iraq.

(3) *The agency form number, if any, and the applicable component of the department sponsoring the collection:* Form Number: FCSC 1–12. Foreign Claims Settlement Commission, Department of Justice.

(4) *Effected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals. Other: None. Information will be used as a basis to adjudicate eligibility for compensation of U.S. nationals, under the U.S.-Iraq Claims Settlement Agreement and the November 14, 2012 referral to the Commission by the Department of State Legal Adviser, for serious personal injuries, which may include instances of serious physical, mental, or emotional injury arising from sexual assault, coercive interrogation, mock execution, or aggravated physical assault. Awards will be payable by the Department of the Treasury out of funds provided.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that 20 individual respondents will complete the application in approximately two hours each.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated total annual public burden associated with this application is 40 hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Room 3W–1407B, Washington, DC 20530.

Dated: February 5, 2013.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2013–02874 Filed 2–7–13; 8:45 am]

BILLING CODE 4410–BA–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[OMB Number 1117–0006]

Agency Information Collection Activities; Proposed Collection; Comments Requested: Application for Individual Manufacturing Quota for a Basic Class of Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine

ACTION: 30-day notice.

The Department of Justice (DOJ), Drug Enforcement Administration (DEA) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 77, Number 233, page 71831 on December 4, 2012, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until March 11, 2013. This process is conducted in accordance with 5 CFR 1320.10. Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395–7285.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the

use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection 1117–0006

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Application for Individual Manufacturing Quota for a Basic Class of Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine (DEA Form 189).

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: DEA Form 189, Office of Diversion Control, Drug Enforcement Administration, Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit.

Other: None.

Abstract: 21 U.S.C. 826 and 21 CFR 1303.22 and 1315.22 require that any person who is registered to manufacture any basic class of controlled substances listed in Schedule I or II and who desires to manufacture a quantity of such class, or who desires to manufacture using the List I chemicals ephedrine, pseudoephedrine, or phenylpropanolamine, must apply on DEA Form 189 for a manufacturing quota for such quantity of such class or List I chemical.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* DEA estimates that each form takes 0.5 hours (30 minutes) to complete. In total, 33 firms submit 641 responses, with each response taking 0.5 hours (30 minutes) to complete. This results in a total public burden of 320.5 hours annually.

(6) *An estimate of the total public burden (in hours) associated with the collection:* In total, 33 firms submit 641 responses, with each response taking 0.5 hours (30 minutes) to complete. This results in a total public burden of 320.5 hours annually.

If additional information is required contact: Jerri Murray, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, Department of Justice, Two Constitution Square, 145 N Street, NE., Room 3W–1407B, Washington, DC 20530.

Dated: February 5, 2013.

Jerri Murray,

Department Clearance Officer, PRA, United States Department of Justice.

[FR Doc. 2013–02876 Filed 2–7–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[OMB Number 1117–0008]

Agency Information Collection Activities; Proposed Collection; Comments Requested: Application for Procurement Quota for Controlled Substances and Ephedrine, Pseudoephedrine, and Phenylpropanolamine

ACTION: 30-day notice.

The Department of Justice (DOJ), Drug Enforcement Administration (DEA) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 77, Number 233, page 71832 on December 4, 2012, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until March 11, 2013. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395–7285.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection 1117–0008

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Application for Procurement Quota for Controlled Substances and Ephedrine, Pseudoephedrine, and Phenylpropanolamine (DEA Form 250).

(3) *Agency form number, if any, and the applicable component of the Department sponsoring the collection:* DEA Form 250, Office of Diversion Control, Drug Enforcement Administration, Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other: None.

Abstract: 21 U.S.C. 826 and 21 CFR 1303.12 and 1315.32 require that U.S. companies who desire to use any basic class of controlled substances listed in Schedule I or II or the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine for purposes of manufacturing during the next calendar year shall apply on DEA Form 250 for procurement quota for such class or List I chemical.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* DEA estimates that each form takes ½ hour to complete. DEA estimates that 419 individual respondents will respond to this form. DEA estimates that 2,716 responses are received annually.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total public burden for this collection is 1,358 hours annually.

If additional information is required contact: Jerri Murray, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, Department of Justice, Two Constitution Square, 145 N Street NE., Room 3W–1407B, Washington, DC 20530.

Dated: February 5, 2013.

Jerri Murray,

Department Clearance Officer, PRA, United States Department of Justice.

[FR Doc. 2013–02877 Filed 2–7–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[OMB Number 1117–0033]

Agency Information Collection Activities; Proposed Collection; Comments Requested: Report of Mail Order Transaction

ACTION: 30-day notice.

The Department of Justice (DOJ), Drug Enforcement Administration (DEA), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 77, Number 236, page 73052, on December 7, 2012, allowing for a 60-day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until March 11, 2013. This process is conducted in accordance with 5 CFR 1320.10. Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395–7285.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of Information Collection 1117–0033

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Report of Mail Order Transaction.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: none; Office of Diversion Control, Drug Enforcement Administration, Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief* abstract:

Primary: Business or other for-profit.

Other: Not-for-Profit Institutions; State, Local or Tribal Government.

Abstract: The Comprehensive Methamphetamine Control Act of 1996 (Pub. L. 104–237) (MCA) amended the Controlled Substances Act to require that each regulated person who engages in a transaction with a non-regulated person which involves ephedrine, pseudoephedrine, or phenylpropanolamine (including drug products containing these chemicals) and uses or attempts to use the Postal Service or any private or commercial carrier shall, on a monthly basis, submit a report of each such transaction conducted during the previous month to the Attorney General.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that there are 11 total respondents for this information collection; three (3) for paper form at 1 hour for each response; and eight (8) via electronic mail at 15 minutes per form, all of which report monthly. The total annual burden is 60 hours (36 hours for paper forms and 24 hours for electronic forms).

(6) *An estimate of the total public burden (in hours) associated with the collection:* It is estimated that there are 60 annual burden hours associated with this collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Room 3W–1407B, Washington, DC 20530.

Dated: February 5, 2013.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2013–02875 Filed 2–7–13; 8:45 am]

BILLING CODE 4410–09–P

LEGAL SERVICES CORPORATION

Sunshine Act Meeting Notice

DATE AND TIME: The Legal Services Corporation's Institutional Advancement Committee will meet telephonically on February 13, 2013. The meeting will commence at 4:00 p.m., Eastern Standard Time (EST), and will continue until the conclusion of the Committee's agenda.

LOCATION: F. William McCalpin Conference Center, Legal Services Corporation Headquarters, 3333 K Street NW., Washington, DC 20007.

STATUS OF MEETING: Closed. Upon a vote of the Board of Directors, the meeting may be closed to the public to receive a presentation on and to discuss prospective funders for LSC's development activities and 40th anniversary celebration.

A verbatim written transcript will be made of the closed session of the Board and Institutional Advancement Committee meetings. The transcript of any portions of the closed session falling within the relevant provisions of the Government in the Sunshine Act, 5 U.S.C. § 552b(c)(9) will not be available for public inspection. A copy of the General Counsel's Certification that, in his opinion, the closing is authorized by law will be available upon request.

Matters To Be Considered

1. Presentation on and discussion of prospective funders for LSC's development activities and 40th anniversary celebration

2. Consider and act on adjournment of meeting

CONTACT PERSON FOR INFORMATION: Katherine Ward, Executive Assistant to the Vice President & General Counsel, at (202) 295–1628. Questions may be sent by electronic mail to *FR_NOTICE_QUESTIONS@lsc.gov.*

ACCESSIBILITY: LSC complies with the Americans with Disabilities Act and Section 504 of the 1973 Rehabilitation Act. Upon request, meeting notices and materials will be made available in alternative formats to accommodate individuals with disabilities.

Individuals who need other accommodations due to disability in order to attend the meeting in person or telephonically should contact Atitaya Rok, at (202) 295–1500 or *FR_NOTICE_QUESTIONS@lsc.gov,* at least 2 business days in advance of the meeting. If a request is made without advance notice, LSC will make every effort to accommodate the request but cannot guarantee that all requests can be fulfilled.

Dated: February 6, 2013.

Kara Ward,

Assistant General Counsel.

[FR Doc. 2013–03067 Filed 2–6–13; 4:15 pm]

BILLING CODE 7050–01–P

MERIT SYSTEMS PROTECTION BOARD

Notice of Opportunity To File Amicus Briefs

AGENCY: Merit Systems Protection Board.

ACTION: Notice.

SUMMARY: The Merit Systems Protection Board (MSPB or Board) announces the opportunity to file amicus briefs in the matter of *Thomas F. Day* v. *Department of Homeland Security,* MSPB Docket Number SF–1221–12–0528–W–1, currently pending before the Board on interlocutory appeal. The administrative judge certified for interlocutory review the question of whether the provisions of the Whistleblower Protection Enhancement Act of 2012 (WPEA), 112 Public Law 199, may be applied retroactively to pending cases involving conduct occurring prior to its effective date.

Of particular relevance in *Day* is the question of the retroactive effect of section 101(b)(2)(B) of the WPEA, which provides in relevant part that a disclosure made to an alleged wrongdoer or during an employee's normal course of duties is not excluded from protection against reprisal under 5 U.S.C. 2302(b)(8). In *Huffman* v. *Office of Personnel Management,* 263 F.3d 1341, 1352 (Fed. Cir. 2001), the U.S. Court of Appeals for the Federal Circuit held that a disclosure made as part of an employee's normal duties, and through normal channels, was not protected under the Whistleblower Protection Act (WPA). The court in *Huffman* further held that a complaint made to a supervisor regarding the supervisor's own alleged wrongdoing was not protected under the WPA. *Id.* at 1350. The Board has applied the holdings in *Huffman* as binding precedent. *See, e.g., Stiles* v. *Department of Homeland Security,* 116 M.S.P.R. 263, ¶ 15 (2011). Therefore, the Board must determine in *Day* whether to apply the WPEA standard or the *Huffman* standard in determining whether disclosures that occurred prior to the effective date of the WPEA are entitled to protection. Information about the *Day* case and the WPEA may be found on the Board's Web site at *www.mspb.gov/SignificantCases.*

Interested individuals or organizations may submit amicus briefs or other comments on the question presented in *Day* no later than March 1, 2013. Amicus briefs must be filed with the Clerk of the Board. Briefs shall not exceed 30 pages in length. The text shall be double-spaced, except for quotations and footnotes, and the briefs shall be on 8½ by 11 inch paper with one inch margins on all four sides. All amicus briefs received will be posted on the Board's Web site at *www.mspb.gov/SignificantCases* after March 1, 2013.

DATES: All briefs submitted in response to this notice must be received by the Clerk of the Board on or before March 1, 2013.

ADDRESSES: All briefs shall be captioned ''*Thomas F. Day* v. *Department of Homeland Security*'' and entitled ''Amicus Brief.'' Only one copy of the brief need be submitted. The Board encourages interested parties to submit amicus briefs as attachments to electronic mail addressed to *mspb@mspb.gov.* An email should contain a subject line indicating that the submission contains an amicus brief in the *Day* case. Any commonly-used word processing format or PDF format is acceptable; text formats are preferable to image formats. Briefs may also be filed with William D. Spencer, Clerk of the Board, Merit Systems Protection Board, 1615 M Street NW., Washington, DC 20419; Fax (202) 653–7130.

FOR FURTHER INFORMATION CONTACT: Molly Leckey, Office of the Clerk of the Board, Merit Systems Protection Board, 1615 M Street NW., Washington, DC 20419; (202) 653–7200; *mspb@mspb.gov.*

William D. Spencer,

Clerk of the Board.

[FR Doc. 2013–02879 Filed 2–7–13; 8:45 am]

BILLING CODE 7400–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Information Security Oversight Office

National Industrial Security Program Policy Advisory Committee (NISPPAC)

AGENCY: National Archives and Records Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act (5 U.S.C. app 2) and implementing regulation 41 CFR 101–6, announcement is made for the following committee meeting to discuss National Industrial Security Program policy matters.

DATES: The meeting will be held on March 20, 2013 from 10:00 a.m. to 12:00 p.m.

ADDRESSES: National Archives and Records Administration, 700 Pennsylvania Avenue NW., Archivist's Reception Room, Room 105, Washington, DC 20408.

SUPPLEMENTARY INFORMATION: This meeting will be open to the public. However, due to space limitations and access procedures, the name and telephone number of individuals planning to attend must be submitted to the Information Security Oversight Office (AISOO) no later than Friday, March 15, 2013. ISOO will provide additional instructions for gaining access to the location of the meeting.

FOR FURTHER INFORMATION CONTACT: David O. Best, Senior Program Analyst, ISOO, National Archives Building, 700 Pennsylvania Avenue NW., Washington, DC 20408, telephone number (202) 357–5123, or at *david.best@nara.gov.* Contact ISOO at *ISOO@nara.gov* and the NISPPAC at *NISPPAC@nara.gov.*

Dated: February 4, 2013.

Patrice Little Murray,

Acting Committee Management Officer.

[FR Doc. 2013–02884 Filed 2–7–13; 8:45 am]

BILLING CODE 7515–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2011–0081; Docket No. 70–3098; Construction Authorization No. CAMOX–001]

Shaw AREVA MOX Services, LLC (Mixed Oxide Fuel Fabrication Facility); Order Approving Indirect Transfer of Control of Construction Authorization

I

Shaw AREVA MOX Services, LLC (MOX Services) holds Construction

Authorization (CA) CAMOX–001 for construction of a Mixed Oxide (MOX) Fuel Fabrication Facility (MFFF) at the U.S. Department of Energy (DOE) Savannah River Site in Aiken, South Carolina.

II

By letter dated August 30, 2012, as supplemented by letters dated October 1, 2012, December 20, 2012, and January 16, 2013, and a purchase transaction agreement dated July 30, 2012 (together, the Transfer Application), MOX Services requested that the U.S. Nuclear Regulatory Commission (NRC) consent to the proposed indirect transfer of Construction Authorization (''CA'') CAMOX–001 that would be effected by the indirect transfer of control of Shaw Environmental & Infrastructure, Inc.'s (''Shaw E&I'') 30% interest, and Shaw Project Services Group, LLC's (''SPSG'') 40% interest in MOX Services. The transfer will occur as a result of the purchase of Shaw E&I and SPSG's ultimate parent company, The Shaw Group Inc. (''Shaw''), by Chicago Bridge and Iron Company NV (''CB&I''), pursuant to a purchase transaction agreement. MOX Services would continue to hold the CA. Upon completion of the transaction, Shaw will become a wholly owned subsidiary of CB&I. Shaw holds a 70% ownership interest in MOX Services through its subsidiaries, Shaw E&I and SPSG. In addition, DOE is requiring that a proxy agreement be established pursuant to the policies duly authorized under the National Industrial Security Program. The proxy agreement will give control of CB&I's interest in MOX Services to SPSG, as a proxy for CB&I, Shaw, and Shaw E&I, in order to insulate SPSG and MOX Services from any potential Foreign Ownership, Control or Influence (FOCI) in order to maintain the Facility Security Clearance held by MOX Services. No physical changes to the MFFF are being proposed.

Approval of the indirect transfer of the CA was requested pursuant to Section 184 of the Atomic Energy Act of 1954, as amended (AEA) (42 U.S.C. 2234) and Section 70.36 of Title 10 of the *Code of Federal Regulations* (10 CFR). A notice of the request for approval and opportunity for a hearing or to submit written comments was published in the **Federal Register** on October 25, 2012 (77 FR 65208). No comments or requests for a hearing were received in response to this notice. The **Federal Register** notice was corrected on (January 30, 2013; 78 FR 6356) to fix a typographical error.

Pursuant to Section 184 of the AEA, no license granted under the AEA, and pursuant to 10 CFR 70.36, no license granted under 10 CFR part 70, shall be transferred, assigned, or in any manner disposed of, directly or indirectly, through transfer of control of any license to any person unless the Commission, after securing full information, finds that the transfer is in accordance with the provisions of the AEA, and gives its consent in writing. The CA does not authorize MOX Services to use Special Nuclear Material at the MFFF; it only authorizes MOX Services to construct the MFFF. The CA is analogous to a construction permit, and it has served as the mechanism under which the NRC staff has overseen the MFFF construction activities. The Commission's regulations at 10 CFR 2.4, define ''license'' as including a construction permit. Therefore, the CA is analogous to a license and the requirements of Section 184 of the AEA and 10 CFR 70.36 are applicable to this action.

Upon review of the information received from MOX Services, and other information before the Commission, and relying upon the representations and agreements contained in the Transfer Application, the NRC staff finds that (1) it has secured full information regarding the proposed indirect transfer of control of CAMOX–001, and (2) the proposed indirect transfer, to the extent that CB&I will acquire a 70% ownership interest in MOX Services pursuant to its planned acquisition of Shaw, as described in the Transfer Application, and to the extent that CB&I, Shaw, Shaw E&I, SPSG, and MOX Services are in compliance with DOE FOCI requirements for maintenance of the MFFF DOE Facility Security Clearance, is in accordance with the provisions of the AEA of 1954, as amended.

The findings set forth above are supported by a Safety Evaluation (SE) dated January 30, 2013.

III

Accordingly, pursuant to Section 184 of the AEA Act of 1954, as amended and Section 70.36 of 10 CFR, *it is hereby ordered* that the indirect transfer of control of CAMOX–001, as described herein, is approved.

It is further ordered that after receipt of all required regulatory approvals of the proposed indirect transfer, MOX Services shall inform the Director of the Office of Nuclear Material Safety and Safeguards, in writing, of such receipt no later than one (1) business day prior to the closing of the proposed indirect transfer. Should the proposed indirect transfer not be completed within 60 days from the date of issuance of this Order, the Order shall become null and void; however, on written application and for good cause shown, such date may be extended by order.

This Order is effective upon issuance.

For further details with respect to this Order, see the letter dated August 30, 2012, as amended, (which can be found at Agencywide Documents Access and Management System [ADAMS] Accession Number ML12243A498). Publicly-available records will be accessible electronically from the ADAMS Public Electronic Reading Room on the Internet at the NRC Web site *http://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff by telephone at 1–800–397–4209, or 301–415–4737 or by email to *pdr@nrc.gov.*

Dated at Rockville, Maryland this 31st day of January 2013.

For the Nuclear Regulatory Commission.

Catherine Haney,

Director, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2013–02873 Filed 2–7–13; 8:45 am]

BILLING CODE 7590–01–P

RAILROAD RETIREMENT BOARD

Agency Forms Submitted for OMB Review, Request for Comments

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Railroad Retirement Board (RRB) is forwarding an Information Collection Request (ICR) to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB). Our ICR describes the information we seek to collect from the public. Review and approval by OIRA ensures that we impose appropriate paperwork burdens.

The RRB invites comments on the proposed collection of information to determine (1) The practical utility of the collection; (2) the accuracy of the estimated burden of the collection; (3) ways to enhance the quality, utility, and clarity of the information that is the subject of collection; and (4) ways to minimize the burden of collections on respondents, including the use of automated collection techniques or other forms of information technology. Comments to the RRB or OIRA must contain the OMB control number of the ICR. For proper consideration of your comments, it is best if the RRB and OIRA receive them within 30 days of the publication date.

Section 2 of the Railroad Retirement Act (RRA) provides for payment of

disability annuities to qualified employees and widow(ers). The establishment of permanent disability for work in the applicants ''regular occupation'' or for work in any regular employment is prescribed in 20 CFR 220.12 and 220.13 respectively.

The RRB utilizes Form G–251, *Vocational Report,* to obtain an applicant's work history. This information is used by the RRB to determine the effect of a disability on an applicant's ability to work. Form G–251 is designed for use with the RRB's disability benefit application forms and is provided to all applicants for employee disability annuities and to those applicants for a widow(er)'s disability annuity who indicate that they have been employed at some time.

Completion is required to obtain or retain a benefit. One response is requested of each respondent.

Previous Requests for Comments: The RRB has already published the initial 60-day notice (77 FR 63358 on October 16, 2012) required by 44 U.S.C. 3506(c)(2). That request elicited no comments.

Information Collection Request (ICR)

Title: Vocational Report
OMB Control Number: 3220–0141
Form(s) submitted: G–251
Type of request: Extension without change of a currently approved collection

Affected public: Individuals or Households

Abstract: Section 2 of the Railroad Retirement Act provides for the payment of disability annuities to qualified employees and widow(er)s. In order to determine the effect of a disability on an annuitant's ability to work, the RRB needs the applicant's work history. The collection obtains the information needed to determine their ability to work.

Changes proposed: The RRB proposes no changes to Form G–251.

The burden estimate for the ICR is as follows:

Form No.	Annual responses	Time (minutes)	Burden (hours)
G–251 (with assistance)	5,730	30	2,865
G–251 (without assistance)	270	40	180
Total	6,000		3,045

Additional Information or Comments: Copies of the forms and supporting documents can be obtained from Dana Hickman at (312) 751–4981 or *Dana.Hickman@RRB.GOV*.

Comments regarding the information collection should be addressed to Charles Mierzwa, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois, 60611–2092 or *Charles.Mierzwa@RRB.GOV* and to the OMB Desk Officer for the RRB, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov*.

Charles Mierzwa,

Chief of Information Resources Management.

[FR Doc. 2013–02856 Filed 2–7–13; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235–0378, SEC File No. 270–332]

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:
Form F–8.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Form F–8 (17 CFR 239.38) may be used to register securities of certain Canadian issuers under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) that will be used in an exchange offer or business combination. The information collected is intended to ensure that the information required to be filed by the Commission permits verification of compliance with securities law requirements and assures the public availability of such information. The information provided is mandatory and all information is made available to the public upon request. We estimate that Form F–8 takes approximately one hour per response to prepare and is filed by approximately 10 respondents. We estimate that 25% of one hour per response (15 minutes) is prepared by the company for a total annual reporting burden of 3 hours (15 minutes/60 minutes per response × 10 responses = 2.5 hours rounded to 3 hours).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: February 4, 2013.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–02849 Filed 2–7–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235–0120, SEC File No. 270–108]

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:
Form 18–K.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget this

request for extension of the previously approved collection of information discussed below.

Form 18–K (17 CFR 249.318) is an annual report form used by foreign governments or political subdivisions of foreign governments with securities listed on a United States exchange. The information to be collected is intended to ensure the adequacy of information available to investors in the registration of securities and assures public availability. The information provided is mandatory. Form 18–K is a public document. We estimate that Form 18–K takes approximately 8 hours to prepare and is filed by approximately 40 respondents for a total annual reporting burden of 320 hours.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: February 4, 2013.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–02853 Filed 2–7–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235–0382, SEC File No. 270–339]

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Schedule 14D–9F.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Schedule 14D–9F (17 CFR 240.14d–103) under the Securities Exchange Act of 1934 (15 U.S.C. 78 *et seq.*) is used by any foreign private issuer incorporated or organized under the laws of Canada or by any director or officer of such issuer, where the issuer is the subject of a cash tender or exchange offer for a class of securities filed on Schedule 14D–1F. The information required to be filed with the Commission is intended to permit verification of compliance with the securities law requirements and assures the public availability of such information. The information provided is mandatory and all information is made available to the public upon request. We estimate that Schedule 14D–9F takes approximately 2 hours per response to prepare and is filed by approximately 6 respondents annually for a total reporting burden of 12 hours.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: February 4, 2013.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–02851 Filed 2–7–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235–0109, SEC File No. 270–116]

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extensions:

Rule 12d1–3.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Exchange Act Rule 12d1–3 (17 CFR 240.12d1–3) requires a certification that a security has been approved by an exchange for listing and registration pursuant to Section 12(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78l(d)) to be filed with the Commission. The information required under Rule 12d1–3 must be filed with the Commission and is publicly available. We estimate that it takes approximately one-half hour to provide the information required under Rule 12d1–3 and that the information is filed by approximately 688 respondents annually for a total annual reporting burden of 344 burden hours (0.5 hours per response × 688 responses).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: February 4, 2013.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–02847 Filed 2–7–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235–0383, SEC File No. 270–331]

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Form F–7.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Form F–7 (17 CFR 239.37) is a registration statement under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) used to register securities that are offered for cash upon the exercise of rights granted to a registrant's existing security holders to purchase or subscribe such securities. The information collected is intended to ensure that the information required to be filed by the Commission permits verification of compliance with securities law requirements and assures the public availability of such information. The information provided is mandatory and all information is made available to the public upon request. Form F–7 takes approximately 4 hours per response to prepare and is filed by approximately 5 respondents. We estimate that 25% of 4 hours per response (one hour) is prepared by the company for a total annual reporting burden of 5 hours (one hour per response × 5 responses).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: February 4, 2013.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–02848 Filed 2–7–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235–0379, SEC File No. 270–336]

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Form F–X.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Form F–X (17 CFR 239.42) is used to appoint an agent for service of process by Canadian issuers registering securities on Forms F–7, F–8, F–9 or F–10 under the Securities Act of 1933 (U.S.C. 77a *et seq.*), or filing periodic reports on Form 40–F under the Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The information collected must be filed with the Commission and is publicly available. We estimate that it takes approximately 2 hours per response to prepare Form F–X and that the information is filed by approximately 161 respondents for a total annual reporting burden of 322 hours (2 hours per response × 161 responses).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: February 4, 2013.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–02850 Filed 2–7–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235–0069, SEC File No. 270–069]

Submission for OMB Review; Comment Request

Upon Written Request; Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Industry Guides.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget this requests for extension of the previously approved collections of information discussed below.

Industries Guides are used by registrants in certain industries as disclosure guidelines to be followed in presenting information to investors in Securities Act (15 U.S.C. 77a *et seq.*) and Exchange Act (15 U.S.C. 78a *et seq.*) registration statements and certain other Exchange Act filings. The paperwork burden from the Industry Guides is imposed through the forms that are subject to the disclosure requirements in the Industry Guides and is reflected in the analysis of these documents. To avoid a Paperwork Reduction Act inventory reflecting duplicative burdens, for administrative convenience

the Commission estimates the total annual burden imposed by the Industry Guides to be one hour. The information required by the Industry Guides is filed on occasion and is mandatory. All information is provided to the public. The Industry Guides do not directly impose any disclosure burden.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: February 4, 2013.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–02852 Filed 2–7–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68820; File No. SR–PHLX–2013–12]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend a Pilot Program Related to Rule 3312, Entitled ''Clearly Erroneous Transactions''

February 1, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 [2] thereunder, notice is hereby given that on January 31, 2013, NASDAQ OMX PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Commission a proposal to extend a pilot program related to Rule 3312, entitled ''Clearly Erroneous Transactions.'' The Exchange also proposes to adopt new paragraph (g) to Rule 3312 in connection with the upcoming operation of the Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS under the Act (the ''Limit Up-Limit Down Plan'' or ''Plan'').[3]

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqomxphlx.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to extend the effectiveness of the Exchange's current rule applicable to Clearly Erroneous Transactions and to adopt new paragraph (g) to Rule 3312 in connection with upcoming operation of the Limit Up-Limit Down Plan.

Proposal To Extend Pilot

Portions of Rule 3312, explained in further detail below, are currently operating as a pilot program set to expire on February 4, 2013.[4] The Exchange proposes to extend the pilot program to September 30, 2013.

On September 10, 2010, the Commission approved, on a pilot basis, changes to Exchange Rule 3312 to provide for uniform treatment: (1) Of clearly erroneous transaction reviews in multi-stock events involving twenty or more securities; and (2) in the event transactions occur that result in the issuance of an individual stock trading pause by the primary market and subsequent transactions that occur before the trading pause is in effect on the Exchange.[5] The Exchange also adopted additional changes to Rule 3312 that reduced the ability of the Exchange to deviate from the objective standards set forth in Rule 3312.[6] The Exchange believes the benefits to market participants from the more objective clearly erroneous transactions rule should continue on a pilot basis through September 30, 2013, which is the date that the Exchange anticipates that the phased implementation of the Limit Up-Limit Down Plan will be complete. As explained in further detail below, although the Limit Up-Limit Down Plan is intended to prevent transactions that would need to be nullified as clearly erroneous, the Exchange believes that certain protections should be maintained while the industry gains initial experience operating with the Limit Up-Limit Down Plan, including the provisions of Rule 3312 that currently operate as a pilot.

Proposed Limit Up-Limit Down Provision to Rule 3312

The Exchange proposes to adopt new paragraph (g) to Rule 3312, to provide that the existing provisions of Rule 3312 will continue to apply to all Exchange transactions, including transactions in securities subject to the Plan, other than as set forth in proposed paragraph (g). Accordingly, other than as proposed below, the Exchange proposes to maintain and continue to apply the Clearly Erroneous Transaction standards in the same way that it does today. Notably, this means that the Exchange might nullify transactions that occur within the price bands disseminated pursuant to the Limit Up-Limit Down Plan to the extent such transactions qualify as clearly erroneous under existing criteria. As an example, assume that a Tier 1 security pursuant to the Plan has a reference price pursuant to both the Plan and Rule 3312 of $100.00. The lower pricing band under the Plan

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012) (the ''Limit Up-Limit Down Release'').

[4] *See* Securities Exchange Act Release No. 67538 (July 30, 2012), 77 FR 46548 (August 3, 2012) (SR–PHLX–2012–100).

[5] *See* Securities Exchange Act Release No. 63491 (December 9, 2010), 75 FR 78297 (December 15, 2010) (SR–PHLX–2010–173).

[6] *Id.*

would be $95.00 and the upper pricing band under the Plan would be $105.00. An execution could occur on the Exchange in this security at $96.00, as this is within the Plan's pricing bands. However, if subjected to review as potentially clearly erroneous, the Exchange would nullify an execution at $96.00 as clearly erroneous because it exceeds the 3% threshold that is in place pursuant to Rule 3312(a)(2)(C)(i) for securities priced above $50.00 (*i.e.,* with a reference price of $100.00, any transactions at or below $97.00 or above $103.00 could be nullified as clearly erroneous). Accordingly, this proposal maintains the status quo with respect to reviews of Clearly Erroneous Transactions and the application of objective numerical guidelines by the Exchange. The proposal does not increase the discretion afforded to the Exchange in connection with reviews of Clearly Erroneous Transactions.

The Limit Up-Limit Down Plan is designed to prevent executions from occurring outside of dynamic price bands disseminated to the public by the single plan processor as defined in the Limit Up-Limit Down Plan.[7] The possibility remains that the Exchange could experience a technology or systems problem with respect to the implementation of the price bands disseminated pursuant to the Plan. To address such possibilities, the Exchange proposes to adopt language to make clear that if an Exchange technology or systems issue results in any transaction occurring outside of the price bands disseminated pursuant to the Plan, a Senior Official of the Exchange, acting on his or her own motion or at the request of a third party, shall review and declare any such trades null and void. Absent extraordinary circumstances, any such action of the Senior Official of the Exchange shall be taken in a timely fashion, generally within thirty (30) minutes of the detection of the erroneous transaction. When extraordinary circumstances exist, any such action of the Senior Official of the Exchange must be taken by no later than the start of Regular Trading Hours [8] on the trading day following the date on which the execution(s) under review occurred. Although the Exchange will act as promptly as possible and the proposed objective standard (*i.e.,* whether an execution occurred outside the band) should make it feasible to quickly make a determination, there may be circumstances in which additional time may be needed for verification of facts or coordination with outside parties, including the single plan processor responsible for disseminating the price bands and other market centers. Accordingly, the Exchange believes it necessary to maintain some flexibility to make a determination outside of the thirty (30) minute guideline. In addition, the Exchange proposes that a transaction that is nullified pursuant to new paragraph (g) would be appealable in accordance with the provisions of Rule 3312(c). In addition, the Exchange proposes to make clear that in the event that a single plan processor experiences a technology or systems problem that prevents the dissemination of price bands, the Exchange would make the determination of whether to nullify transactions based on Rule 3312(a)–(f).

The Exchange believes that cancelling trades that occur outside of the price bands disseminated pursuant to the Plan is consistent with the purpose and intent of the Plan, as such transactions are not intended to occur in the first place. If transactions do occur outside of the price bands and no exception applies—which necessarily would be caused by a technology or systems issue—then the Exchange believes the appropriate result is to nullify such transactions.

2. Statutory Basis

The Exchange believes that its proposal is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[9] In particular, the proposal is consistent with Section 6(b)(5) of the Act,[10] because it would promote just and equitable principles of trade, remove impediments to, and perfect the mechanism of, a free and open market and a national market system. The Exchange believes that the pilot program promotes just and equitable principles of trade in that it promotes transparency and uniformity across markets concerning review of transactions as clearly erroneous. More specifically, the Exchange believes that the extension of the pilot would help assure that the determination of whether a clearly erroneous trade has occurred will be based on clear and objective criteria, and that the resolution of the incident will occur promptly through a transparent process. The proposed rule change would also help assure consistent results in handling erroneous trades across the U.S. markets, thus furthering fair and orderly markets, the protection of investors and the public interest. Although the Limit Up-Limit Down Plan will be operational during the same time period as the proposed extended pilot, the Exchange believes that maintaining the pilot for at least through the phased implementation of the Plan is operational will help to protect against unanticipated consequences. To that end, the extension will allow the Exchange to determine whether Rule 3312 is necessary once the Plan is operational and, if so, whether improvements can be made. Further, the Exchange believes it consistent with the protection of investors and the public interest to adopt objective criteria to nullify transactions that occur outside of the Plan's price bands when such transactions should not have been executed but were due to a systems or technology issue.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change implicates any competitive issues. To the contrary, the Exchange believes that FINRA and other national securities exchanges are also filing similar proposals, and thus, that the proposal will help to ensure consistent rules across market centers.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [11] and Rule 19b–4(f)(6)(iii) thereunder.[12]

[7] *See* Limit Up-Limit Down Release, *supra* note 3.

[8] Regular Trading Hours commence at 9:30 a.m. Eastern Time. *See* Exchange Rule 3312(a)(2)(B).

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6)(iii). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date

Continued

The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the pilot program to continue uninterrupted, thereby avoiding the investor confusion that could result from a temporary interruption in the pilot program. For this reason, the Commission designates the proposed rule change to be operative upon filing.[13]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–PHLX–2013–12 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–PHLX–2013–12. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–PHLX–2013–12, and should be submitted on or before March 1, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–02800 Filed 2–7–13; 8:45 am]

BILLING CODE 8011–01–P

of filing of the proposed rule change, or such shorter time as designated by the Commission.

[13] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68819; File No. SR–NASDAQ–2013–022]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Extend a Pilot Program Related to Rule 11890, Entitled ''Clearly Erroneous Transactions''

February 1, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 [2] thereunder, notice is hereby given that on January 31, 2013, The NASDAQ Stock Market LLC (''NASDAQ'' or ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by NASDAQ. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

NASDAQ is filing with the Commission a proposal to extend a pilot program related to Rule 11890, entitled ''Clearly Erroneous Transactions.'' The Exchange also proposes to adopt new paragraph (g) to Rule 11890 in connection with the upcoming operation of the Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS under the Act (the ''Limit Up-Limit Down Plan'' or ''Plan'').[3]

The text of the proposed rule change is available from NASDAQ's Web site at *http://nasdaq.cchwallstreet.com,* at NASDAQ's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NASDAQ included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. NASDAQ has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to extend the effectiveness of the Exchange's current rule applicable to Clearly Erroneous Transactions and to adopt new paragraph (g) to Rule 11890 in connection with upcoming operation of the Limit Up-Limit Down Plan.

Proposal To Extend Pilot

Portions of Rule 11890, explained in further detail below, are currently operating as a pilot program set to expire on February 4, 2013.[4] The Exchange proposes to extend the pilot program to September 30, 2013.

On September 10, 2010, the Commission approved, on a pilot basis, changes to NASDAQ Rule 11890 to provide for uniform treatment: (1) Of

[3] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012) (the ''Limit Up-Limit Down Release'').

[4] *See* Securities Exchange Act Release No. 67536 (July 30, 2012), 77 FR 46541 (August 3, 2012) (SR–NASDAQ–2012–091).

clearly erroneous transaction reviews in multi-stock events involving twenty or more securities; and (2) in the event transactions occur that result in the issuance of an individual stock trading pause by the primary market and subsequent transactions that occur before the trading pause is in effect on the Exchange.[5] The Exchange also adopted additional changes to Rule 11890 that reduced the ability of the Exchange to deviate from the objective standards set forth in Rule 11890.[6] The Exchange believes the benefits to market participants from the more objective clearly erroneous transactions rule should continue on a pilot basis through September 30, 2013, which is the date that the Exchange anticipates that the phased implementation of the Limit Up-Limit Down Plan will be complete. As explained in further detail below, although the Limit Up-Limit Down Plan is intended to prevent transactions that would need to be nullified as clearly erroneous, the Exchange believes that certain protections should be maintained while the industry gains initial experience operating with the Limit Up-Limit Down Plan, including the provisions of Rule 11890 that currently operate as a pilot.

Proposed Limit Up-Limit Down Provision to Rule 11890

The Exchange proposes to adopt new paragraph (g) to Rule 11890, to provide that the existing provisions of Rule 11890 will continue to apply to all Exchange transactions, including transactions in securities subject to the Plan, other than as set forth in proposed paragraph (g). Accordingly, other than as proposed below, the Exchange proposes to maintain and continue to apply the Clearly Erroneous Transaction standards in the same way that it does today. Notably, this means that the Exchange might nullify transactions that occur within the price bands disseminated pursuant to the Limit Up-Limit Down Plan to the extent such transactions qualify as clearly erroneous under existing criteria. As an example, assume that a Tier 1 security pursuant to the Plan has a reference price pursuant to both the Plan and Rule 11890 of $100.00. The lower pricing band under the Plan would be $95.00 and the upper pricing band under the Plan would be $105.00. An execution could occur on the Exchange in this security at $96.00, as this is within the Plan's pricing bands. However, if subjected to review as potentially clearly erroneous, the Exchange would nullify an execution at $96.00 as clearly erroneous because it exceeds the 3% threshold that is in place pursuant to Rule 11890(a)(2)(C)(1) for securities priced above $50.00 (*i.e.,* with a reference price of $100.00, any transactions at or below $97.00 or above $103.00 could be nullified as clearly erroneous). Accordingly, this proposal maintains the status quo with respect to reviews of Clearly Erroneous Transactions and the application of objective numerical guidelines by the Exchange. The proposal does not increase the discretion afforded to the Exchange in connection with reviews of Clearly Erroneous Transactions.

The Limit Up-Limit Down Plan is designed to prevent executions from occurring outside of dynamic price bands disseminated to the public by the single plan processor as defined in the Limit Up-Limit Down Plan.[7] The possibility remains that the Exchange could experience a technology or systems problem with respect to the implementation of the price bands disseminated pursuant to the Plan. To address such possibilities, the Exchange proposes to adopt language to make clear that if an Exchange technology or systems issue results in any transaction occurring outside of the price bands disseminated pursuant to the Plan, a Senior Official of the Exchange, acting on his or her own motion or at the request of a third party, shall review and declare any such trades null and void. Absent extraordinary circumstances, any such action of the Senior Official of the Exchange shall be taken in a timely fashion, generally within thirty (30) minutes of the detection of the erroneous transaction. When extraordinary circumstances exist, any such action of the Senior Official of the Exchange must be taken by no later than the start of Regular Trading Hours[8] on the trading day following the date on which the execution(s) under review occurred. Although the Exchange will act as promptly as possible and the proposed objective standard (*i.e.,* whether an execution occurred outside the band) should make it feasible to quickly make a determination, there may be circumstances in which additional time may be needed for verification of facts or coordination with outside parties, including the single plan processor responsible for disseminating the price bands and other market centers. Accordingly, the Exchange believes it necessary to maintain some flexibility to make a determination outside of the thirty (30) minute guideline. In addition, the Exchange proposes that a transaction that is nullified pursuant to new paragraph (g) would be appealable in accordance with the provisions of Rule 11890(c). In addition, the Exchange proposes to make clear that in the event that a single plan processor experiences a technology or systems problem that prevents the dissemination of price bands, the Exchange would make the determination of whether to nullify transactions based on Rule 11890(a)–(f).

The Exchange believes that cancelling trades that occur outside of the price bands disseminated pursuant to the Plan is consistent with the purpose and intent of the Plan, as such transactions are not intended to occur in the first place. If transactions do occur outside of the price bands and no exception applies—which necessarily would be caused by a technology or systems issue—then the Exchange believes the appropriate result is to nullify such transactions.

2. Statutory Basis

The Exchange believes that its proposal is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[9] In particular, the proposal is consistent with Section 6(b)(5) of the Act,[10] because it would promote just and equitable principles of trade, remove impediments to, and perfect the mechanism of, a free and open market and a national market system. The Exchange believes that the pilot program promotes just and equitable principles of trade in that it promotes transparency and uniformity across markets concerning review of transactions as clearly erroneous. More specifically, the Exchange believes that the extension of the pilot would help assure that the determination of whether a clearly erroneous trade has occurred will be based on clear and objective criteria, and that the resolution of the incident will occur promptly through a transparent process. The proposed rule change would also help assure consistent results in handling erroneous trades across the U.S. markets, thus furthering fair and orderly markets, the protection of investors and the public interest. Although the Limit Up-Limit

[5] *See* Securities Exchange Act Release No. 62886 (September 10, 2010), 75 FR 56613 (September 16, 2010) (SR–NASDAQ–2010–076).

[6] *Id.*

[7] *See* Limit Up-Limit Down Release, supra note 3.

[8] Regular Trading Hours commence at 9:30 a.m. Eastern Time. *See* NASDAQ Rule 11890(a)(2)(B).

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

Down Plan will be operational during the same time period as the proposed extended pilot, the Exchange believes that maintaining the pilot for at least through the phased implementation of the Plan is operational will help to protect against unanticipated consequences. To that end, the extension will allow the Exchange to determine whether Rule 11890 is necessary once the Plan is operational and, if so, whether improvements can be made. Further, the Exchange believes it consistent with the protection of investors and the public interest to adopt objective criteria to nullify transactions that occur outside of the Plan's price bands when such transactions should not have been executed but were due to a systems or technology issue.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change implicates any competitive issues. To the contrary, the Exchange believes that FINRA and other national securities exchanges are also filing similar proposals, and thus, that the proposal will help to ensure consistent rules across market centers.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [11] and Rule 19b–4(f)(6)(iii) thereunder.[12]

The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the pilot program to continue uninterrupted, thereby avoiding the investor confusion that could result from a temporary interruption in the pilot program. For this reason, the Commission designates the proposed rule change to be operative upon filing.[13]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2013–022 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2013–022. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2013–022, and should be submitted on or before March 1, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–02799 Filed 2–7–13; 8:45 am]

BILLING CODE 8011–01–P

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b 4(f)(6)(iii). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

[13] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68822; File No. SR–ISE–2013–12]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by International Securities Exchange, LLC To Amend ISE Rule 2128 Relating to Clearly Erroneous Trades

February 4, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b-4 thereunder,[2] notice is hereby given that on February 1, 2013, the International Securities Exchange, LLC (the ''Exchange'' or the ''ISE'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 2128 (Clearly Erroneous Trades) to extend the expiration of the pilot rule. The Exchange also proposes to adopt

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b-4.

new paragraph (i) to Rule 2128 in connection with the upcoming operation of the Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS under the Act (the ''Limit Up-Limit Down Plan'' or ''Plan'').[3]

The text of the proposed rule change is available on the Exchange's Internet Web site at *http://www.ise.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend ISE Rule 2128 (Clearly Erroneous Trades) to extend the expiration of the pilot rule to September 30, 2013 and to adopt new paragraph (i) to Rule 2128 in connection with upcoming operation of the Limit Up-Limit Down Plan. Amendments to ISE Rule 2128 to provide for uniform treatment of certain clearly erroneous execution reviews in multi-stock events involving twenty or more securities and in the event transactions occur that result in the issuance of an individual stock trading pause by the primary market and subsequent transactions that occur before a trading pause is in effect on the Exchange were approved by the Commission on September 10, 2010 on a pilot basis to end on April 11, 2011.[4] The Exchange then extended this pilot to expire upon the earlier of August 11, 2011 or the date on which the limit up/limit down mechanism to address extraordinary market volatility applies.[5] The Exchange then extended the pilot to January 31, 2012[6] and, once again, extended the pilot to July 31, 2012.[7] On July 27, 2012, ISE Rule 2102 [sic] was amended to extend the pilot to February 4, 2013.[8] The Exchange now proposes to extend the date by which this pilot rule will expire to September 30, 2013, which is the date that the Exchange anticipates that the phased implementation of the Limit Up-Limit Down Plan will be complete.

As explained in further detail below, although the Limit Up-Limit Down Plan is intended to prevent executions that would need to be nullified as clearly erroneous, the Exchange believes that certain protections should be maintained while the industry gains initial experience operating with the Limit Up-Limit Down Plan, including the provisions of Rule 11.17 that currently operate as a pilot.

Proposed Limit Up-Limit Down Provision to Rule 11.17

The Exchange proposes to adopt new paragraph (i) to Rule 2128, to provide that the existing provisions of Rule 2128 will continue to apply to all Exchange transactions, including transactions in securities subject to the Plan, other than as set forth in proposed paragraph (i). Accordingly, other than as proposed below, the Exchange proposes to maintain and continue to apply the Clearly Erroneous trade standards in the same way that it does today. Notably, this means that the Exchange might nullify transactions that occur within the price bands disseminated pursuant to the Limit Up-Limit Down Plan to the extent such transactions qualify as clearly erroneous under existing criteria. As an example, assume that a Tier 1 security pursuant to the Plan has a reference price pursuant to both the Plan and Rule 2128 of $100.00. The lower pricing band under the Plan would be $95.00 and the upper pricing band under the Plan would be $105.00. An execution could occur on the Exchange in this security at $96.00, as this is within the Plan's pricing bands. However, if subjected to review as potentially clearly erroneous, the Exchange would nullify an execution at $96.00 as clearly erroneous because it exceeds the 3% threshold that is in place pursuant to Rule 2128(c)(1) for securities priced above $50.00 (*i.e.,* with a reference price of $100.00, any transactions at or below $97.00 or above $103.00 could be nullified as clearly erroneous). Accordingly, this proposal maintains the status quo with respect to reviews of Clearly Erroneous Executions and the application of objective numerical guidelines by the Exchange. The proposal does not increase the discretion afforded to the Exchange in connection with reviews of Clearly Erroneous Executions.

The Limit Up-Limit Down Plan is designed to prevent executions from occurring outside of dynamic price bands disseminated to the public by the single plan processor as defined in the Limit Up-Limit Down Plan.[9] The possibility remains that the Exchange could experience a technology or systems problem with respect to the implementation of the price bands disseminated pursuant to the Plan. To address such possibilities, the Exchange proposes to adopt language to make clear that if an Exchange technology or systems issue results in any transaction occurring outside of the price bands disseminated pursuant to the Plan, an Officer of the Exchange or senior level employee designee, acting on his or her own motion or at the request of a third party, shall review and declare any such trades null and void. Absent extraordinary circumstances, any such action of the Officer of the Exchange or other senior level employee designee shall be taken in a timely fashion, generally within thirty (30) minutes of the detection of the erroneous transaction. When extraordinary circumstances exist, any such action of the Officer of the Exchange or other senior level employee designee must be taken by no later than the start of Regular Market Session[10] on the trading day following the date on which the execution(s) under review occurred. Although the Exchange will act as promptly as possible and the proposed objective standard (*i.e.,* whether an execution occurred outside the band) should make it feasible to quickly make a determination, there may be circumstances in which additional time may be needed for verification of facts or coordination with outside parties, including the single plan processor responsible for disseminating the price bands and other market centers. Accordingly, the Exchange believes it

[3] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012) (the ''Limit Up-Limit Down Release'').

[4] *See* Securities Exchange Act Release Nos. 62886 (September 10, 2010), 75 FR 56613 (September 16, 2010) (SR–ISE–2010–62) (Extending the pilot period to December 10, 2010); 63481 (December 9, 2010), 75 FR 78275 (December 15, 2010) (Extending the pilot period to April 11, 2011).

[5] *See* Securities and Exchange Act Release No. 64231 (April 7, 2011), 76 FR 20733 (April 13, 2011) (SR–ISE–2011–19).

[6] *See* Securities and Exchange Act Release No. 65061 (August 9, 2011), 76 FR 50503 (August 15, 2011) (SR–ISE–2011–51).

[7] *See* Securities and Exchange Act Release No. 66255 (January 26, 2012), 77 FR 5081 (February 1, 2012) (SR–ISE–2012–04).

[8] *See* Securities Exchange Act Release No. 67528 (July 27, 2012), 77 FR 46532 (August 3, 2012) (SR–ISE–2012–67).

[9] *See* Limit Up-Limit Down Release, *supra* note 3.

[10] Regular Market Session commence [sic] at 9:30 a.m. Eastern Time. *See* ISE Rules 2102 and 2106.

necessary to maintain some flexibility to make a determination outside of the thirty (30) minute guideline. In addition, the Exchange proposes that a transaction that is nullified pursuant to new paragraph (i) would be appealable in accordance with the provisions of Rule 2128(e)(2). In addition, the Exchange proposes to make clear that in the event that a single plan processor experiences a technology or systems problem that prevents the dissemination of price bands, the Exchange would make the determination of whether to nullify transactions based on Rule 2128(a)–(h).

The Exchange believes that cancelling trades that occur outside of the price bands disseminated pursuant to the Plan is consistent with the purpose and intent of the Plan, as such transactions are not intended to occur in the first place. If transactions do occur outside of the price bands and no exception applies—which necessarily would be caused by a technology or systems issue—then the Exchange believes the appropriate result is to nullify such transactions.

2. Statutory Basis

The statutory basis for the proposed rule change is Section 6(b)(5) of the Act,[11] which requires the rules of an exchange to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. The Exchange believes that the pilot program promotes just and equitable principles of trade in that it promotes transparency and uniformity across markets concerning review of transactions as clearly erroneous. More specifically, the Exchange believes that the extension of the pilot would help assure that the determination of whether a clearly erroneous trade has occurred will be based on clear and objective criteria, and that the resolution of the incident will occur promptly through a transparent process. The proposed rule change would also help assure consistent results in handling erroneous trades across the U.S. markets, thus furthering fair and orderly markets, the protection of investors and the public interest. Although the Limit Up-Limit Down Plan will be operational during the same time period as the proposed extended pilot, the Exchange believes that maintaining the pilot for at least through the phased implementation of the Plan is operational will help to protect against unanticipated consequences. To that end, the extension will allow the Exchange to determine whether Rule 2128 is necessary once the Plan is operational and, if so, whether improvements can be made. Further, the Exchange believes it consistent with the protection of investors and the public interest to adopt objective criteria to nullify transactions that occur outside of the Plan's price bands when such transactions should not have been executed but were due to a systems or technology issue.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[12] and Rule 19b–4(f)(6)(iii) thereunder.[13]

The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the pilot program to continue uninterrupted, thereby avoiding the investor confusion that could result from a temporary interruption in the pilot program. For this reason, the Commission designates the proposed rule change to be operative upon filing.[14]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ISE–2013–12 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2013–12. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room on official business days between the hours of 10:00 a.m.

[11] 15 U.S.C. 78f(b)(5).

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(6)(iii). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

[14] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2013–12, and should be submitted on or before March 1, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Kevin M. O'Neill,

Deputy Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68823; File Nos. SR–BSECC–2012–002; SR–BX–2012–075; SR–NASDAQ–2012–142; SR–Phlx–2012–142; SR–SCCP–2012–02]

Self-Regulatory Organizations; Boston Stock Exchange Clearing Corporation; NASDAQ OMX BX, Inc.; the NASDAQ Stock Market LLC; NASDAQ OMX PHLX LLC; Stock Clearing Corporation of Philadelphia; Order Approving Proposed Rule Changes With Respect to the Amendment of the By-Laws of The NASDAQ OMX Group, Inc.

February 4, 2013.

I. Introduction

On December 19, 2012, Boston Stock Exchange Clearing Corporation (''BSECC''), NASDAQ OMX BX, Inc. (''BX''), the NASDAQ Stock Market LLC (''NASDAQ''), NASDAQ OMX PHLX LLC (''Phlx''), and the Stock Clearing Corporation of Philadelphia (''SCCP'' and, together with BSECC, BX, NASDAQ and Phlx, the ''SROs'' or ''Self-Regulatory Subsidiaries''), filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act''),[2] and Rule 19b–4 thereunder,[3] proposed rule changes with respect to the amendment of the by-laws (''NASDAQ OMX By-Laws'') of the NASDAQ OMX Group, Inc. (''NASDAQ OMX''), the parent company of the SROs. The proposed rule changes were published for comment in the **Federal Register** on December 31, 2012 with respect to the BX, NASDAQ and Phlx proposals and on January 2, 2013 with respect to the SCCP and BSECC proposals.[4] The Commission received no comment letters on the proposals.

The Commission has reviewed carefully the proposed rule changes and finds that the proposed rule changes are consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange in the case of the proposals by BX, NASDAQ and Phlx and to a clearing agency in the case of the proposals by BSECC and SCCP.[5] In particular, the Commission finds that the proposed rule changes by BX, NASDAQ and Phlx are consistent with Section 6(b)(1) of the Act,[6] which, among other things, requires a national securities exchange to be so organized and have the capacity to be able to carry out the purposes of the Act and to comply, and enforce compliance by its members and persons associated with its members, with the provisions of the Act, the rules and regulations thereunder and the rules of the exchange. In addition, the Commission finds that the proposed rule changes by BX, NASDAQ and Phlx are consistent with Section 6(b)(5) of the Act,[7] which, among other things, requires that the rules of the exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission also finds that the proposed rule changes by BSECC and SCCP are consistent with Section 17A of the Act,[8] which, among other things, requires that the rules of a clearing agency are designed to facilitate the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, to assure the safeguarding of securities and funds in its custody or control or for which it is responsible, and to protect investors and the public interest.

II. Discussion and Commission Findings

Definitions of Directors

The SROs are proposing amendments to provisions of the NASDAQ OMX By-Laws pertaining to the compositional requirements of the Board of Directors of NASDAQ OMX (''NASDAQ OMX Board''). The SROs propose to amend the definition of ''Industry Director.'' Under the proposed definition, an Industry Director and ''Industry committee member''[9] will be defined as a Director who: (1) Is, or within the last year was, or has an immediately family member[10] who is, or within the last year was, a member of a Self-Regulatory Subsidiary;[11] (2) is, or within the last year was, employed by a member or a member organization of a Self-Regulatory Subsidiary;[12] (3) has an immediate family member who is, or within the last year was, an executive officer of a member or a member organization[13] of a Self-Regulatory Subsidiary; (4) has within the last year received from any member or member organization of a Self-Regulatory

[15] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release Nos. 68512 (December 21, 2012), 77 FR 77168 (December 31, 2012) (SR–NASDAQ–2012–142) (''NASDAQ Notice''); 68513 (December 21, 2012), 77 FR 77129 (December 31, 2012) (SR–Phlx–2012–142); 68514 (December 21, 2012), 77 FR 77137 (December 31, 2012) (SR–BX–2012–075); 68536 (December 26, 2012), 78 FR 128 (January 2, 2013) (SR–SCCP–2012–02); 68537 (December 26, 2012), 78 FR 132 (January 2, 2013) (SR–BSECC–2012–002).

[5] In approving the proposed rule changes, the Commission has considered their impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[6] 15 U.S.C. 78f(b)(1).

[7] 15 U.S.C. 78f(b)(5).

[8] 15 U.S.C. 78q–1(b)(3)(F).

[9] The term ''committee member'' in the NASDAQ OMX By-Laws refers to membership in the committees authorized under Section 4.13 of the By-Laws, such as the Executive Committee and the Audit Committee. Under the NASDAQ OMX By-Laws and the Delaware General Corporation Law, all members of committees with the power and authority to act on behalf of the NASDAQ OMX Board in the management of the business and affairs of NASDAQ OMX must themselves be Directors. Accordingly, the definitions of ''Industry Director'' and ''Industry committee member'' are coterminous as applied to any member of these committees. The NASDAQ OMX By-Laws do not presently contemplate any committees with non-Director members.

[10] A definition of ''immediate family member'' will be added to the NASDAQ OMX By-Laws as follows: '' 'Immediate family member' means a person's spouse, parents, children and siblings, whether by blood, marriage or adoption, or anyone residing in such person's home.'' The definition is identical to the definition of ''family member'' contained in NASDAQ listing standards, as provided in NASDAQ Rule 5605.

[11] This provision will apply to an individual that is or was a member of Phlx, the only Self-Regulatory Subsidiary that allows natural persons to become members.

[12] A broker-dealer that is admitted to membership in Phlx is referred to as a ''member organization;'' broker-dealers admitted to membership in the other Self-Regulatory Subsidiaries are referred to as ''members.''

[13] An ''Executive Officer'' of a member or member organization means those officers covered in Rule 16a–1(f) under the Act, as if the member or member organization were an issuer within the meaning of such Rule. 17 CFR 240.16a–1(f).

Subsidiary more than $100,000 per year in direct compensation, or received from such members or member organizations in the aggregate an amount of direct compensation that in any one year is more than 10 percent of the Director's annual gross compensation for such year, excluding in each case director and committee fees and pension or other forms of deferred compensation for prior service (provided such compensation is not contingent in any way on continued service); or (5) is affiliated, directly or indirectly, with a member or member organization of a Self-Regulatory Subsidiary.

According to the SROs, the current definition of Industry Director focuses on a Director's affiliation with any broker-dealer, regardless of whether the broker-dealer is a member or member organization of a Self-Regulatory Subsidiary, and features a three-year ''look-back'' period during which a Director formerly associated with a broker-dealer would continue to be deemed an Industry Director.[14] According to the SROs, the proposed definition of Industry Director is less restrictive than the current definition but will continue to serve the purpose of ensuring that members and member organizations of Self-Regulatory Subsidiaries [15]—the self-regulatory organizations owned by NASDAQ OMX—do not have disproportionate influence on its governance.[16] Moreover, the SROs state that the change is warranted to ensure that the definition of Industry Director is appropriately focused on the mitigation of potential conflicts of interest associated with Directors who are currently or were very recently employed by members or member organizations of Self-Regulatory Subsidiaries, or that otherwise have material affiliations with such members or member organizations, without unnecessarily restricting highly qualified individuals with extensive knowledge of the financial services industry from serving on the NASDAQ OMX Board.[17] Further, the SROs note that NASDAQ OMX is incorporating concepts from recently-approved changes to the Independence Policy of NYSE Euronext.[18]

In addition, the SROs propose changes to other definitions applicable to categories of Directors. Specifically, the SROs propose to add a definition of ''Staff Director'' as ''an officer of the Corporation that is serving as a Director.'' [19] According to the SROs, this change will further restrict the number of possible Staff Directors in instances where the NASDAQ OMX Board is smaller than ten Directors, while retaining the current limit of two Staff Directors for a larger NASDAQ OMX Board.[20]

The SROs also propose to add a definition of ''Issuer Director'' and ''Issuer committee member'' as ''a Director (excluding any Staff Director) or committee member who is an officer or employee of an issuer of securities listed on a national securities exchange operated by any Self-Regulatory Subsidiary, excluding any Director or committee member who is a director of such an issuer but is not also an officer or employee of such an issuer.'' According to the SROs, the exclusion of Staff Directors from the definition is necessary because NASDAQ OMX is listed on NASDAQ, but the purpose of the NASDAQ OMX By-Laws in requiring issuer representation to promote a diversity of viewpoints among Directors would not be well served by deeming Staff Directors also to be Issuer Directors.[21] The SROs also state that the proposed definition of Issuer Director and Issuer committee member would exclude persons who are directors of issuers but who are not also officers or employees of such issuers, which is intended to make clear that a Director is not barred from being considered a Public Director merely because the Director serves as an independent director of another listed company.[22]

The SROs also propose to amend the definition of ''Public Director'' and ''Public committee member'' to state: ''A Director or committee member who (1) is not an Industry Director or Industry committee member, (2) is not an Issuer Director or Issuer committee member, and (3) has no material business relationship with a member or member organization of a Self-Regulatory Subsidiary, the Corporation or its affiliates, or FINRA.'' [23] The current definition covers a person who ''has no material business relationship with a broker or dealer, the Corporation or its affiliates, or FINRA.'' [24] According to the SROs, the proposed definition makes clear that any Industry Director or Issuer Director would not be considered a Public Director, but an independent director of an issuer of securities listed on NASDAQ could be considered a Public Director.[25] The SROs also state that in keeping with the change to the definition of Industry Director discussed above, the final clause of the definition of Public Director would be revised to focus on the existence of a material business relationship with a member or member organization of a Self-Regulatory Subsidiary, rather than any broker or dealer.

In addition, the SROs propose changing the definition of ''Non-Industry Director'' or ''Non-Industry committee member'' to cover any ''Director (excluding any Staff Director) or committee member who is (1) a Public Director or Public committee member; (2) an Issuer Director or Issuer committee member; or (3) any other individual who would not be an Industry Director or Industry committee member.'' [26] According to the SROs, this revised definition is generally consistent with the current definition, but reflects the new definition of ''Issuer Director'' and ''Issuer committee member.'' [27]

The SROs believe that the foregoing definitional changes will enhance the clarity of these provisions and will promote a diversity of backgrounds and viewpoints on the NASDAQ OMX Board, and will collectively promote the capacity of the NASDAQ OMX Board to fulfill its responsibilities.[28]

The Commission finds that the BX, NASDAQ and Phlx proposals are consistent with the Act, particularly Sections 6(b)(1) and (b)(5) of the Act. The Commission also finds that the BSECC and SCCP proposals are consistent with Section 17A of the Act. The Commission believes that these proposed definitional changes to the NASDAQ OMX By-Laws will help to ensure that potential conflicts of interest with respect to the composition of the NASDAQ OMX Board will continue to

[14] *See, e.g.,* NASDAQ Notice, 77 FR at 77168.

[15] The NASDAQ OMX By-Laws define each of NASDAQ, BX, Phlx, BSECC, and SCCP as a ''Self-Regulatory Subsidiary.''

[16] *See, e.g.,* NASDAQ Notice, 77 FR at 77168.

[17] *See id.,* 77 FR at 77171.

[18] *See* Securities Exchange Act Release No. 67564 (August 1, 2012), 77 FR 47161) (SR–NYSE–2012–17; SR–NYSEArca–2012–59; SR–NYSEMKT–2012–07).

[19] The SROs note that the definition of ''Industry Director'' will continue to exclude Staff Directors, who might otherwise be considered Industry Directors by virtue of affiliation with NASDAQ Exchange Services LLC and NASDAQ Options Services, LLC, registered broker-dealers that are members of NASDAQ and BX and member organizations of Phlx. *See, e.g.,* NASDAQ Notice, 77 FR at 77169 n.12.

[20] *See, e.g.,* NASDAQ Notice, 77 FR at 77169.

[21] *See, e.g.,* NASDAQ Notice, 77 FR at 77169.

[22] *See, e.g., id.*

[23] *See, e.g., id.*

[24] *See, e.g., id.*

[25] *See, e.g., id.*

[26] *See, e.g.,* NASDAQ Notice, 77 FR at 77170.

[27] Due to the above described changes and the addition of a term ''Issuer Director,'' the SROs proposed making conforming changes to the letter designations of paragraphs in the NASDAQ OMX By-Laws.

[28] *See, e.g.,* NASDAQ Notice, 77 FR at 77169.

be mitigated and at the same time will help promote the capacity of NASDAQ OMX, which is the parent company of the Self-Regulatory Subsidiaries, to fulfill its responsibilities.

Qualifications of Directors

The SROs propose to amend Section 4.3 of the NASDAQ OMX By-Laws, which governs the qualifications and compositional requirements of the NASDAQ OMX Board. Specifically, the changes to the composition of the NASDAQ OMX Board will (i) increase from one to two the required number of Public Directors, (ii) replace the requirement to include at least one issuer representative (or at least two issuer representatives if the NASDAQ OMX Board consists of ten or more Directors) with a requirement to include at least one, but no more than two, Issuer Directors and (iii) limit the number of Staff Directors to one, unless the Board consists of ten or more Directors, in which case the number of Staff Directors cannot exceed two. The NASDAQ OMX By-Laws will continue to require that the number of Non-Industry Directors must equal or exceed the number of Industry Directors. As previously mentioned, because the term ''Issuer Director'' is a new definition, the SROs also propose to make a conforming change by adding that term to Sections 4.8 and 4.13(h) of NASDAQ OMX's By-Laws, which govern the filling of vacancies on the NASDAQ OMX Board and the determination of Directors' qualifications by NASDAQ OMX's Secretary.

The Commission finds that the proposed changes by BX, NASDAQ and Phlx regarding the qualifications and compositional requirements of the NASDAQ OMX Board are consistent with the Act, particularly Sections 6(b)(1) and (b)(5) of the Act. The Commission also finds that the proposed rule changes by BSECC and SCCP regarding the qualifications and compositional requirements of the NASDAQ OMX Board are consistent with Section 17A of the Act. The Commission concurs with the SROs that the proposals will continue to ensure a diversity of representation among Industry, Staff, Issuer, and Public Directors, will place more stringent caps on the number of Issuer and Staff Directors, and will increase the requirement regarding the number of Public Directors.[29] Further, as noted by the SROs, the proposed rule changes do not alter in any respect the compositional requirements imposed by NASDAQ listing standards on NASDAQ OMX as a NASDAQ listed issuer, particularly the requirement that the NASDAQ OMX Board be composed of a majority of independent directors.[30]

Executive Committee

The SROs propose to amend the compositional requirement of NASDAQ OMX's Executive Committee, which is authorized by Section 4.13(d) of the NASDAQ OMX By-Laws. Under the proposed rule changes, NASDAQ OMX's By-Laws will be amended to require that there be at least two Public Directors on the Executive Committee (as opposed to the current requirement that the percentage of Public Directors on the Executive Committee must be at least as great as the percentage of Public Directors on the NASDAQ OMX Board).[31]

The Commission finds that this proposal is consistent with the Act, particularly Sections 6(b)(1) and (b)(5) of the Act. The Commission also finds that the proposed rule changes are consistent with Section 17A of the Act. The Commission believes that the proposal to amend the compositional requirement of NASDAQ OMX's Executive Committee will continue to ensure a diversity of representation among Directors serving on the Executive Committee and will help to ensure that potential conflicts of interest with respect to the composition of the NASDAQ OMX Board will continue to be mitigated.

Audit Committee

The SROs also proposed changes to the composition requirements of the NASDAQ OMX Audit Committee. Under the proposed rule changes to the compositional requirements of the Audit Committee, Section 4.13(g) of NASDAQ OMX's By-Laws will be amended to reflect that the number of Non-Industry Directors on the Audit Committee must be equal to or exceed the number of Industry Directors (as opposed to the current requirement that the Audit Committee be composed of a majority of Non-Industry Directors). The SROs state that the proposed compositional requirements for the Audit Committee with regard to the balance between Industry Directors and Non-Industry Directors will be consistent with the compositional requirements currently provided for in the NASDAQ OMX By-Laws with respect to NASDAQ OMX's Executive Committee, Nominating & Governance Committee, Management Compensation Committee,[32] and the NASDAQ OMX Board. According to the SROs, this change will provide greater flexibility to NASDAQ OMX with regard to populating the Audit Committee with Directors having relevant expertise and will ensure that the Audit Committee is not too large in relation to the size of the NASDAQ OMX Board, while continuing to ensure that Directors associated with members and member organizations of the Self-Regulatory Subsidiaries do not exert disproportionate influence on the governance of NASDAQ OMX.[33]

The Commission finds that this proposal is consistent with the Act, particularly Sections 6(b)(1) and (b)(5) of the Act. The Commission also finds that the proposed rule changes are consistent with Section 17A of the Act.

[29] *See, e.g.,* NASDAQ Notice, 77 FR at 77170.

[30] NASDAQ Rule 5605 requires that the board of directors of a company listed on NASDAQ must have a majority of directors that are ''independent'' within the meaning of that rule. As provided in NASDAQ Rule 5605(a)(2) with respect to a company listed on NASDAQ (''Company''), '''Independent Director' means a person other than an Executive Officer or employee of the Company or any other individual having a relationship which, in the opinion of the Company's board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.'' NASDAQ Rule 5605 further provides that directors having certain defined relationships with a Company may not be considered independent. The SROs note that, while Staff Directors are clearly not independent within the meaning of NASDAQ Rule 5605, other Directors may or may not be considered independent, depending on the specific facts of their relationship to NASDAQ OMX.

[31] *See, e.g.,* NASDAQ Notice, 77 FR at 77170.

[32] As a listed company on NASDAQ, NASDAQ OMX must also comply with NASDAQ's listing rules, which contain certain provisions that require Independent Directors to serve on such company's board of directors and on various board committees. *See supra* note 30 for a summary of the definition of Independent Director as set forth in NASDAQ Rule 5605(a)(2). Among other requirements in NASDAQ's listing rules, a listed company's compensation committee must be comprised solely of such Independent Directors. The Commission recently approved amendments that NASDAQ proposed in order for NASDAQ to comply with Rule 10C–1 under the Act. The new rules require, among other things, that members of a listed company's compensation committee must meet enhanced independence requirements, in addition to having to be Independent Directors as defined in NASDAQ's existing listing rules. NASDAQ's listed companies must comply with these enhanced independence requirements at the earlier of the company's first annual meeting after January 15, 2014 or October 31, 2014. *See* NASDAQ Rule 5605(d) and Securities Exchange Act Release No. 68640 (January 11, 2013), 78 FR 4554 (January 22, 2013).

The Commission notes that the SROs' proposed rule changes are not intended to address whether a particular Industry or Non-Industry Director would qualify under the NASDAQ's definition as an Independent Director or could qualify as a compensation committee member under the newly-adopted enhanced standards of independence for compensation committee service. As for any listed company, NASDAQ OMX will have to do its own assessment of whether a particular director qualifies as an Independent Director for service on the listed company's board or board committees, particularly the audit, compensation, or nomination committees, under NASDAQ's listing standards.

[33] *See, e.g.,* NASDAQ Notice 77 FR 77170.

The Commission believes that the proposal will help to ensure that potential conflicts of interest with respect to the composition of the NASDAQ OMX Board will continue to be mitigated and at the same time will help promote the capacity of NASDAQ OMX to fulfill its responsibilities.

The Commission notes that the proposed rule changes will not alter NASDAQ OMX's obligations under Section 10A of the Act [34] and SEC Rule 10A–3 thereunder,[35] which relate to audit committee requirements of listed issuers. According to the SROs, the NASDAQ OMX Audit Committee will continue to be composed solely of Directors who are independent within the meaning of Section 10A and Rule 10A–3 thereunder. Under NASDAQ Rule 5605(c), the NASDAQ OMX Audit Committee is required to be comprised of Independent Directors (as defined in NASDAQ's Rule 5605(a)(2)). The Commission notes that the NASDAQ OMX Audit Committee's members also must meet the independence requirements of Section 10A of the Act and Rule 10A–3 thereunder.

III. Conclusion

For the foregoing reasons, the Commission finds that the proposed rule changes are consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange in the case of BX, NASDAQ and Phlx and with the Act and rules and regulations thereunder applicable to a registered clearing agency in the case of BSECC and SCCP.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act [36] that the proposed rule changes (SR–BSECC–2012–02; SR–BX–2012–075; SR–NASDAQ–2012–142; SR–Phlx–2012–142; SR–SCCP–2012–02) are approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[37]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–02846 Filed 2–7–13; 8:45 am]

BILLING CODE 8011–01–P

[34] 15 U.S.C. 78j–1.

[35] 17 CFR 240.10A–3.

[36] 15 U.S.C. 78f(b)(2).

[37] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

Advance Nanotech, Inc., Advanced ID Corp., Aeon Holdings, Inc. (n/k/a BCM Energy Partners, Inc.), ANTS Software, Inc., Beauty Brands Group, Inc., Beijing Century Health Medical, Inc., Chocolate Candy Creations, Inc., Crystallex International Corp., Dermaxar, Inc., Dragon International Group Corp., e-SIM, Ltd., EcoReady Corp., EnDevCo, Inc., Electronic Kourseware International, Inc., Ensign Services, Inc., and eTelCharge.com, Inc.; Order of Suspension of Trading

February 6, 2013.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Advanced Nanotech, Inc. because it has not filed any periodic reports since the period ended September 30, 2010.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Advanced ID Corp. because it has not filed any periodic reports since the period ended September 30, 2009.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Aeon Holdings, Inc. (n/k/a BCM Energy Partners, Inc.) because it has not filed any periodic reports since the period ended March 31, 2001.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of ANTS Software, Inc. because it has not filed any periodic reports since the period ended March 31, 2011.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Beauty Brands Group, Inc. because it has not filed any periodic reports since the period ended September 30, 2010.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Beijing Century Health Medical, Inc. because it has not filed any periodic reports since the period ended February 28, 2011.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Chocolate Candy Creations, Inc. because it has not filed any periodic reports since the period ended March 31, 2011.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Crystallex International Corp. because it has not filed any periodic reports since the period ended December 31, 2010.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Dermaxar, Inc. because it has not filed any periodic reports since the period ended January 31, 2010.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Dragon International Group Corp. because it has not filed any periodic reports since the period ended March 31, 2009.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of e-SIM, Ltd. because it has not filed any periodic reports since the period ended January 31, 2007.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of EcoReady Corp. because it has not filed any periodic reports since the period ended September 30, 2010.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of EnDevCo, Inc. because it has not filed any periodic reports since the period ended March 31, 2010.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Electronic Kourseware International, Inc. because it has not filed any periodic reports since it filed an amended registration statement on March 23, 2009.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Ensign Services, Inc. because it has not filed any periodic reports since the period ended March 31, 2010.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of eTelCharge.com, Inc. because it has not filed any periodic reports since the period ended September 30, 2009.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed companies.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed companies is suspended for the period from 9:30 a.m. EST on February 6, 2013, through 11:59 p.m. EST on February 20, 2013.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2013–02980 Filed 2–6–13; 11:15 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements; 8(a) Annual Update

AGENCY: Small Business Administration.

ACTION: Notice of Information Collection Submitted for OMB Review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to the Office of Management and Budget (OMB) for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission. The information is currently conditionally approved by OMB. SBA is publishing this 30-day notice for public comment to comply with the terms of that conditional approval, which was issued on August 31, 2012. The public is encouraged to submit written comments on this proposed information collection.

DATES: Submit comments on or before March 11, 2013.

ADDRESSES: Address all comments concerning this notice to: *Agency Clearance Officer,* Curtis Rich, Small Business Administration, 409 3rd Street SW., 5th Floor, Washington, DC 20416; and *OMB Reviewer for Small Business Administration,* Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

Copies: Request for copies of the information collection, OMB Form 83–1, supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Curtis Rich, Agency Clearance Officer, *curtis.rich@sba.gov* (202) 205–7030.

SUPPLEMENTARY INFORMATION: This information collection, 8(a) Annual Update, (Form 1450) is submitted by all small businesses participating in SBA's 8(a) Business Development Program (8(a) BD Program), to annually update and report to SBA on the firm's business progress and participation in the program, particularly on the review and update requirements outlined in the SBA regulations at 13 CFR 124.112.

SBA has revised this information collection to, among other things, reflect amendments to the 8(a) BD Program regulations that now require program Participants to report on all 8(a) contracts performed during the previous year, including any such contracts performed as a joint venture, explaining how the performance of work requirements are being met (or have been met); and also, for those Participants in the 8(a) Mentor-Protégé program, to report on services (by category and hours) received from the Mentor. SBA also revised, deleted, or added certain terms (e.g., SAM and DUNS) to conform to current usage; clarified submission of personal information including tax returns, as well as the notification requirements concerning transferred assets.

Title: 8(a) Annual Update.

Frequency: Annual.

SBA Form Number: 1450.

Description of Respondents: Firms that are currently certified as Participant firms in the 8(a) Business Development program.

Estimated Annual Responses: 7,793.

Estimated Annual Hour Burden: 16,099.

Curtis Rich,

Management Analyst.

[FR Doc. 2013–02827 Filed 2–7–13; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments and Recommendations

ACTION: Notice; Extension of comment period for new 8(a) Business Development Program reporting requirements.

SUMMARY: On December 10, 2012, the Small Business Administration (SBA) published the 60-day notice in the **Federal Register** as required by the Paperwork Reduction Act to solicit public comments on new 8(a) Business Development Program reporting requirements. SBA is extending the comment period for this collection information for 30 days to allow interested persons additional time to submit comments.

DATES: Submit comments on or before March 11, 2013.

ADDRESSES: Send all comments to Joan Elliston, Program Analyst, Office of Business Development, U.S. Small Business Administration, 409 3rd Street 8th Floor, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Joan Elliston, Program Analyst, (202) 205–7190, *joan.elliston@sba.gov;* Curtis B. Rich, Management Analyst, (202) 205–7030, *curtis.rich@sba.gov.*

SUPPLEMENTARY INFORMATION: This new collection of information imposes reporting and recordkeeping requirements that will affect small businesses seeking to maintain 8(a) Business Development (BD) program eligibility. To facilitate the reporting of the information, required by 13 CFR 124.604, SBA is creating a new form, ''8(a) Participant Benefits Report.'' The individual 8(a) Participant firm is responsible for completing the form and can furnish its own benefits information or utilize the benefits information offered by its parent corporation. The firm must show how the Tribe, Alaskan Native Corporation (ANC), Native Hawaiian Organization (NHO) or Community Development Corporation (CDC) has provided benefits to the Tribal or native members and/or the Tribal, native or other community due to the Tribe's/ANC's/NHO's/CDC's participation in the 8(a) BD program through one or more firms. This data includes information relating to funding cultural programs, employment assistance, jobs, scholarships, internships, subsistence activities, and other services provided by the Tribe, ANC, NHO or CDC to the affected community.

Comments are invited on: (a) Whether the collection of information is necessary for the Agency to properly perform its functions; (b) the accuracy of the estimated hour burden for the collection of information; (c) ways to enhance the quality, utility, and clarity of the information; and (d) ways to minimize the burden on responding firms.

Title: ''8(a) Participant Benefits Report''.

Description of Respondents: Firms that are currently certified as 8(a) Participant firms in the 8(a) Business Development program and are owned by a Tribe, ANC, NHO, or CDC.

Form Number: N/A.

Annual Responses: 320.

Annual Burden: 480.

Curtis Rich,

Management Analyst.

[FR Doc. 2013–02833 Filed 2–7–13; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #13441 and #13442]

Ohio Disaster Number OH–00039

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Ohio (FEMA–4098–DR), dated 01/03/2013.

Incident: Severe storms and flooding due to the remnants of Hurricane Sandy.

Incident Period: 10/29/2012 through 10/30/2012.

Effective Date: 01/29/2013.

Physical Loan Application Deadline Date: 03/04/2013.

Economic Injury (EIDL) Loan Application Deadline Date: 10/03/2013.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing And Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of OHIO, dated 01/03/2013, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties

Ashtabula.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2013–02826 Filed 2–7–13; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #13473 and #13474]

Arkansas Disaster #AR–00061

AGENCY: U.S. Small Business Administration.

ACTION: Notice

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Arkansas (FEMA–4100–DR), dated 01/29/2013.

Incident: Severe Winter Storm.

Incident Period: 12/25/2012 through 12/26/2012.

Effective Date: 01/29/2013.

Physical Loan Application Deadline Date: 04/01/2013.

Economic Injury (EIDL) Loan Application Deadline Date: 10/29/2013.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 01/29/2013, Private Non-Profit organizations that provide essential services of governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties:

Garland, Grant, Hot Spring, Lonoke, Perry, Pulaski, Saline.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations With Credit Available Elsewhere ...	2.875
Non-Profit Organizations Without Credit Available Elsewhere	2.875
For Economic Injury:	
Non-Profit Organizations Without Credit Available Elsewhere	2.875

The number assigned to this disaster for physical damage is 13473B and for economic injury is 13474B.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2013–02829 Filed 2–7–13; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 8181]

60-Day Notice of Proposed Information Collection: Young Turkey/Young America Evaluation (YTYA) Survey

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to April 9, 2013.

ADDRESSES: You may submit comments by any of the following methods:

- *Web:* Persons with access to the Internet may use the Federal Docket Management System (FDMS) to comment on this notice by going to *www.Regulations.gov*. You can search for the document by entering ''Public Notice ####'' in the Search bar. If necessary, use the Narrow by Agency filter option on the Results page.
- *Email: halemj2@state.gov*.
- *Mail:* ECA/P/V, Department of State (SA–44), 301 4th St. SW., Washington, DC 20547.
- *Fax:* 202–203–7742.
- *Hand Delivery or Courier:* 301 4th St. SW., Washington, DC 20024.

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Michelle Hale, ECA/P/V, Department of State (SA–44), 301 4th St. SW., Washington, DC 20547, who may be reached on 202–203–7205 or at *halemj2@state.gov*.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Young Turkey/Young America Evaluation (YTYA) Survey.
- *OMB Control Number:* None.
- *Type of Request:* New Collection.
- *Originating Office:* Bureau of Educational and Cultural Affairs, ECA/P/V.
- *Form Number:* SV2013–0001.

• *Respondents:* All Turkish and American YTYA Program participants from 2009 to 2011.
• *Estimated Number of Respondents:* 235.
• *Estimated Number of Responses:* 153.
• *Average Time per Response:* 30 minutes.
• *Total Estimated Burden Time:* 77 hours.
• *Frequency:* One time.
• *Obligation to Respond:* Voluntary.

We are soliciting public comments to permit the Department to:

• Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
• Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
• Enhance the quality, utility, and clarity of the information to be collected.
• Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology. Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

This request for a new information collection will allow ECA/P/V to conduct a survey to provide data not currently available. The survey is designed to assess the effectiveness of the YTYA Program in achieving its stated goals and objectives, and assess the outcomes of this two-way, bi-lateral exchange program that included 235 young Turkish and young American participants from 2009 to 2011. This study is authorized by the Mutual Educational and Cultural Exchange Act of 1961, as amended (also known as the Fulbright-Hays Act) (22 U.S.C. 2451 et seq.). The survey will be sent electronically to be completed via web survey to all program participants of the years stated above. Data gathered will enable analysis that can potentially be used to design similar bi-lateral exchange programs, improve existing programs, and to inform ongoing and future exchange programs in ECA.

Methodology

The survey and all notifications will be entirely electronic to ease any burden on the participant. The survey will be distributed and responses received electronically using the survey application Vovici.

Dated: January 31, 2013.

Matt Lussenhop,

Director of the Office of Policy and Evaluation, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2013–02901 Filed 2–7–13; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart B (formerly Subpart Q) during the Week Ending January 26, 2013. The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under Subpart B (formerly Subpart Q) of the Department of Transportation's Procedural Regulations (see 14 CFR 301.201 et seq.). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: DOT–OST–2013–0018.

Date Filed: January 23, 2013.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: February 13, 2013.

Description

Application of Ultimate JETCHARTERS, LLC requesting authority to operate scheduled passenger service as a commuter air carrier.

Barbara J. Hairston,

Acting Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. 2013–02866 Filed 2–7–13; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Noise Exposure Map Notice, Southwest Florida International Airport, Fort Myers, FL

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its determination that the Noise Exposure Maps submitted by the Lee County Port Authority for the Southwest Florida International Airport under the provisions of 49 U.S.C. 47501 et. Seq (Aviation Safety and Noise Abatement Act) and 14 CFR Part 150 are in compliance with applicable requirements.

DATES: This notice is effective February 8, 2013, and is applicable beginning January 30, 2013.

FOR FURTHER INFORMATION CONTACT: Allan Nagy, Federal Aviation Administration, Orlando Airports District Office, 5950 Hazeltine National Drive Citadel International Building, Suite 400, Orlando, FL 32822, 407–812–6331.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA finds that the Noise Exposure Maps submitted for Southwest Florida International Airport are in compliance with applicable requirements of Title 14 Code of Federal Regulations (CFR) Part 150, effective November 15, 2012. Under 49 U.S.C. section 47503 of the Aviation Safety and Noise Abatement Act (the Act), an airport operator may submit to the FAA Noise Exposure Maps which meet applicable regulations and which depict non-compatible land uses as of the date of submission of such maps, a description of projected aircraft operations, and the ways in which such operations will affect such maps. The Act requires such maps to be developed in consultation with interested and affected parties in the local community, government agencies, and persons using the airport. An airport operator who has submitted Noise Exposure Maps that are found by FAA to be in compliance with the requirements of 14 CFR Part 150, promulgated pursuant to the Act, may submit a Noise Compatibility Program for FAA approval which sets forth the measures the airport operator has taken or proposes to take to reduce existing non-compatible uses and prevent the introduction of additional non-compatible uses.

The FAA has completed its review of the Noise Exposure Maps and

accompanying documentation submitted by the Lee County Port Authority. The documentation that constitutes the ''Noise Exposure Maps'' as defined in Section 150.7 of 14 CFR Part 150 includes: Table 4.1, RSW Noise Measurement Locations; Table 7.1, 2011 Annual Operations; Table 7.2, 2011 Annual-Average Day Fleet Mix (Itinerant Operations); Table 7.3, 2011 Annual-Average Day Fleet Mix (Local Operations); Table 7.4, 2017 Annual Operations; Table 7.5, 2017 Annual-Average Day Fleet Mix (Itinerant Operations); Table 7.6, 2017 Annual-Average Day Fleet Mix (Local Operations); Table 7.7, 2011 and 2017 Air Carrier Aircraft Stage Length Percentages; Table 7.8, 2011 Runway Use Percentages; Table 7.9, 2011 and 2017 Departure Flight Track Use Percentages; Table 7.10, 2011 and 2017 Arrival Flight Track Use Percentages; Table 7.11, 2011 and 2017 Local (Touch and Go) Flight Track Use Percentages; Table 8.1, 2012 DNL Contour Surface Areas; Table 8.2, 2017 DNL Contour Surface Areas; Table 8.3, 14 CFR Part 150 Land Use Compatibility Guidelines; Table 8.4, Lee County Airport Noise Zones; Figure 1.2, Airport Location Map; Figure 1.3, Existing Land Uses; Figure 2.1, Airport Diagram; Figure 2–2, U.S. National Airspace System; Figure 2.3, Southwest Florida International Airspace; Figure 2–7, RSW Published Arrivals and Departures; Figure 5.1, RSW RNAV Departures Established Since the 2006 14 CFR Part 150 Study; Figure 5–2, RSW RNAV Arrivals Established Since the 2006 14 CFR Part 150 Study; Figure 5–3, Monthly Operations; Figure 7.1, Modeled Flight Tracks—Northeast Flow; Figure 7.2, Modeled Flight Tracks—Southwest Flow; Figure 7.3, Modeled Flight Tracks—Touch and Go; Figure 8.1, 2012 DNL Noise Contours; Figure 8.2, 2017 DNL Noise Contours; Figure 8.3, Future Land Use; Figure 8.4, Airport Noise Zones; Appendix C, RSW Published IFR Procedures; Appendix L, Map ''A'' 2012 NEM and Map ''B'', 2017; NEM Chapter 9, Page 9–1, Airport Sponsor's Noise Exposure Map Certification; November 1, 2012 Airport Sponsor NEM Submittal Letter.

The FAA has determined that these Noise Exposure Maps and accompanying documentation are in compliance with applicable requirements. This determination is effective on January 30, 2013.

FAA's determination on the airport operator's Noise Exposure Maps is limited to a finding that the maps were developed in accordance with the procedures contained in Appendix A of 14 CFR Part 150. Such determination does not constitute approval of the airport operator's data, information or plans, or a commitment to approve a Noise Compatibility Program or to fund the implementation of that Program. If questions arise concerning the precise relationship of specific properties to noise exposure contours depicted on a Noise Exposure Map submitted under Section 47503 of the Act, it should be noted that the FAA is not involved in any way in determining the relative locations of specific properties with regard to the depicted noise exposure contours, or in interpreting the Noise Exposure Maps to resolve questions concerning, for example, which properties should be covered by the provisions of Section 47506 of the Act. These functions are inseparable from the ultimate land use control and planning responsibilities of local government. These local responsibilities are not changed in any way under 14 CFR Part 150 or through FAA's review of Noise Exposure Maps. Therefore, the responsibility for the detailed overlaying of noise exposure contours onto the map depicting properties on the surface rests exclusively with the airport operator that submitted those maps, or with those public agencies and planning agencies with which consultation is required under Section 47503 of the Act. The FAA has relied on the certification by the airport operator, under Section 150.21 of 14 CFR Part 150, that the statutorily required consultation has been accomplished.

Copies of the full Noise Exposure Maps documentation and of the FAA's evaluation of the maps are available for examination at the following locations: Federal Aviation Administration, Orlando Airports District Office, 5950 Hazeltine National Drive, Citadel International Building, Suite 400, Orlando, FL 32822.

Questions may be directed to the individual named above under the heading, **FOR FURTHER INFORMATION CONTACT**.

Issued in Orlando, FL, on January 30, 2013.

Bart Vernace,

Manager, Orlando Airports District Office, Federal Aviation Administration.

[FR Doc. 2013–02894 Filed 2–7–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35661]

Grand Trunk Western Railroad Company—Acquisition of Operating Easement—CSX Transportation, Inc.

AGENCY: Surface Transportation Board, DOT.

ACTION: Notice of exemption.

SUMMARY: The Board is granting an exemption under 49 U.S.C. 10502 from the prior approval requirements at 49 U.S.C. 11323–25 for Grand Trunk Western Railroad Company (GTW), an indirect, wholly owned subsidiary of Canadian National Railway Company, to acquire from CSX Transportation, Inc. (CSXT) an exclusive, perpetual, non-assignable railroad operating easement over approximately 2.1 miles of CSXT's Memphis Terminal Subdivision, between Leewood, Tenn., milepost 00F371.4, and Aulon, Tenn., milepost 00F373.4 (Leewood-Aulon Line), subject to employee protective conditions. The Leewood-Aulon Line is currently owned by CSXT. Illinois Central Railroad Company, a GTW affiliate, operates over it via trackage rights. Along with the proposed easement acquisition by GTW, CSXT would retain local and overhead trackage rights over the Leewood-Aulon Line.

GTW's easement acquisition is one part of an Agreement for Exchange of Perpetual Easements between GTW and CSXT. In exchange for GTW's acquiring an easement from CSXT over the Leewood-Aulon Line, GTW has agreed to grant CSXT an exclusive, perpetual, non-assignable railroad operating easement over 22.37 miles of GTW track on the Elsdon Subdivision between the connection with CSXT at Munster, Ind., milepost 31.07, and Elsdon, Ill., milepost 8.7, which connects to the southern end of the BNSF Railway Company's Corwith Yard. The Board is separately granting authority for CSXT's acquisition of this operating easement in the Chicago area in Docket Nos. FD 35522 *et al.*[1]

DATES: This exemption will be effective on March 10, 2013. Petitions to stay must be filed by February 19, 2013. Petitions to reopen must be filed by February 28, 2013.

ADDRESSES: Send an original and 10 copies of all pleadings referring to Docket No. FD 35661 to: Surface Transportation Board, 395 E Street SW.,

[1] *See CSX Transp. Inc.—Acquis. of Operating Easement—Grand Trunk W. R.R.,* FD 35522, *et al.* (STB served February 8, 2013).

Washington, DC 20423–0001. In addition, send one copy of pleadings to David A. Hirsh, Harkins Cunningham LLP, 1700 K Street NW., Suite 400, Washington, DC 20006–3804.

FOR FURTHER INFORMATION CONTACT: Scott M. Zimmerman, (202) 245–0386. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at (800) 877–8339.

SUPPLEMENTARY INFORMATION: Additional information is contained in the Board's decision served February 8, 2013, which is available on our Web site at *www.stb.dot.gov.*

Decided: February 4, 2013.

By the Board, Chairman Elliott, Vice Chairman Begeman, and Commissioner Mulvey.

Derrick A. Gardner,

Clearance Clerk.

[FR Doc. 2013–02917 Filed 2–7–13; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. MCF 21049]

Academy Express, L.L.C.—Acquisition of Property—Golden Ring Travel & Transportation, Inc.

AGENCY: Surface Transportation Board, DOT.

ACTION: Notice Tentatively Authorizing Finance Transaction.

SUMMARY: On January 10, 2013, Academy Express, L.L.C. (Academy), a motor carrier of passengers, filed an application for authority under 49 U.S.C. 14303 to acquire the property of Golden Ring Travel & Transportation, Inc. (Golden Ring), also a motor carrier of passengers. The Board is tentatively approving and authorizing the transaction, and, if no opposing comments are timely filed, this notice will be the final Board action. Persons wishing to oppose the application must follow the rules set forth at 49 CFR 1182.5 and 1182.8.

DATES: Comments must be filed by March 25, 2013. Academy may file a reply by April 9, 2013. If no comments are filed by March 25, 2013, this notice shall be effective on March 26, 2013.

ADDRESSES: Send an original and 10 copies of any comments referring to Docket No. MCF 21049 to: Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, send copies of comments to Academy's representative: Fritz R. Kahn, Fritz R. Kahn, P.C., 1919 M Street NW., 7th Floor, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Scott M. Zimmerman, (202) 245–0386. Federal Information Relay Service (FIRS) for the hearing impaired: 1–800–877–8339.

SUPPLEMENTARY INFORMATION: Academy (MC–413682) is a motor carrier of passengers principally providing charter bus and contract carrier services, with a fleet of approximately 400 motor coaches and more than 500 drivers. Academy is indirectly controlled by the Tedesco Family ESB Trust, which also indirectly controls Academy Lines, L.L.C., a motor carrier of passengers principally rendering commuter operations, and No. 22 Hillside, L.L.C., a motor carrier of passengers rendering a variety of services. Golden Ring (MC–233098) is a motor carrier of passengers principally providing special and charter operations and has no affiliates.

Under the proposed transaction, Academy seeks permission to acquire the properties of Golden Ring—namely, three motor coaches, customer lists, and goodwill, as well as Golden Ring's authority to render intrastate motor carrier operations in Maryland. According to the application, Golden Ring would surrender its interstate operating authority and cease operating as an interstate motor carrier of passengers on the effective date of the property acquisition.

Under 49 U.S.C. 14303(b), the Board must approve and authorize a transaction that it finds consistent with the public interest, taking into consideration at least: (1) The effect of the proposed transaction on the adequacy of transportation to the public; (2) the total fixed charges that result; and (3) the interest of affected carrier employees. Academy has submitted information, as required by 49 CFR 1182.2, including the information to demonstrate that the proposed transaction is consistent with the public interest under 49 U.S.C. 14303(b), and a statement that Academy's gross operating revenue for the preceding 12 months exceeded $2 million, *see* 49 U.S.C. 14303(g).

With respect to the effect of the transaction on the adequacy of transportation to the public, Academy states that the proposed acquisition would greatly benefit Golden Ring's patrons. According to Academy, passengers would be able to travel in newer buses and would have a far greater selection of tours and special operations than was previously afforded to them. Academy states that the separate management functions of the two companies would be integrated and the purchases of fuel and other supplies would be combined, thereby lowering the operating costs and rendering the operations formerly conducted by Golden Ring more competitive. Academy further states that the proposed transaction would have no effect on total fixed charges. Academy states that the transaction would have no adverse effect upon the majority of Golden Ring's employees, as most of these employees would retain their jobs.

On the basis of the application, the Board finds that the proposed acquisition is consistent with the public interest and should be tentatively approved and authorized. If any opposing comments are filed by March 25, 2013, these findings will be deemed vacated, and, unless a final decision can be made on the record as developed, a procedural schedule will be adopted to reconsider the application. *See* 49 CFR 1182.6(c). If no opposing comments are filed by the expiration of the comment period, this notice will take effect automatically and will be the final Board action.

Board decisions and notices are available on our Web site at *www.stb.dot.gov.*

This decision will not significantly affect either the quality of the human environment or the conservation of energy resources.

It is ordered:

1. The proposed transaction is approved and authorized, subject to the filing of opposing comments.

2. If opposing comments are timely filed, the findings made in this notice will be deemed vacated.

3. This notice will be effective March 26, 2013, unless opposing comments are timely filed by March 25, 2013.

4. A copy of this notice will be served on: (1) U.S. Department of Transportation, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590; (2) the U.S. Department of Justice, Antitrust Division, 10th Street & Pennsylvania Avenue NW., Washington, DC 20530; and (3) the U.S. Department of Transportation, Office of the General Counsel, 1200 New Jersey Avenue SE., Washington, DC 20590.

Decided: February 4, 2013.

By the Board, Chairman Elliott, Vice Chairman Begeman, and Commissioner Mulvey.

Raina S. White,

Clearance Clerk.

[FR Doc. 2013–02890 Filed 2–7–13; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

February 5, 2013.

The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before March 11, 2013 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestion for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.GOV* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8140, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submission(s) may be obtained by calling (202) 927–5331, email at *PRA@treasury.gov*, or the entire information collection request maybe found at *www.reginfo.gov.*

Internal Revenue Service (IRS)

OMB Number: 1545–0115.

Type of Review: Extension without change of a currently approved collection.

Title: Miscellaneous Income.

Form: 1099 MISC.

Abstract: Form 1099–MISC is used by payers to report payments of $600 or more of rents, prizes and awards, medical and health care payments, nonemployee compensation, and crop insurance proceeds, $10 or more of royalties, any amount of fishing boat proceeds, certain substitute payments, golden parachute payments, and an indication of direct sales of $5,000 or more.

Affected Public: Private Sector: Businesses and other for-profits.

Estimated Total Burden Hours: 24,639,062.

OMB Number: 1545–0118.

Type of Review: Extension without change of a currently approved collection.

Title: Taxable Distributions Received From Cooperatives.

Form: 1099–PATR.

Abstract: Form 1099–PATR is used to report patronage dividends paid by cooperatives (IRC sec. 6044). The information is used by IRS to verify reporting compliance on the part of the recipient.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 509,895.

OMB Number: 1545–2148.

Type of Review: Extension without change of a currently approved collection.

Title: Return of Certain Excise Taxes Under Chapter 43 of the Internal Revenue Code.

Form: 8928.

Abstract: Form 8928 is used by employers, group health plans, HMOs, and third party administrators to report and pay excise taxes due for failures under sections 4980B, 4980D, 4980E, and 4980G.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 2,348.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2013–02878 Filed 2–7–13; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Proposed Information Collection; Comment Request

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. An agency may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. Currently, the OCC is soliciting comment concerning its renewal of an information collection titled, ''Municipal Securities Dealers and Government Securities Brokers and Dealers—Registration and Withdrawal.''

DATES: You should submit written comments by April 9, 2013.

ADDRESSES: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email if possible. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Mail Stop 9W–11, Attention: 1557–0184, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326 or by electronic mail to *regs.comments@occ.treas.gov.* You may personally inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not enclose any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Additionally, please send a copy of your comments by mail to: OCC Desk Officer, 1557–0184, U.S. Office of Management and Budget, 725 17th Street NW., #10235, Washington, DC 20503, or emailed to *oira submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: You can request additional information from or a copy of the collection from Johnny Vilela or Mary H. Gottlieb, Clearance Officers, (202) 649–5490, Legislative and Regulatory Activities Division (1557–0184), Office of the Comptroller of the Currency, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: The OCC is proposing to extend OMB approval of the following information collection:

Title: (MA)—Municipal Securities Dealers and Government Securities Brokers and Dealers—Registration and Withdrawal.

OMB Control No.: 1557–0184.

Form Numbers: MSD, MSDW, MSD–4, MSD–5, G–FIN, G–FINW.

Abstract: This information collection is required to satisfy the requirements of section 15B [1] and section 15C [2] of the Securities Exchange Act of 1934 which require, in part, any national bank or Federal savings association that acts as a government securities broker/dealer or a municipal securities dealer to file the appropriate form with the OCC to

[1] 15 U.S.C. 78o–4.

[2] 15 U.S.C. 78o–5.

inform the agency of its broker/dealer activities. The OCC uses this information to determine which national banks and Federal savings associations are acting as government and municipal securities broker/dealers and to monitor entry into and exit from government and municipal securities broker/dealer activities by institutions and registered persons. The OCC also uses the information in planning national bank and Federal savings association examinations.

Type of Review: Renewal of a currently approved collection. The collection has not changed. The OCC asks only that OMB approve its revised estimates and extend its approval of the forms, revised only to add a clarification to the instructions.

Affected Public: Businesses or other for-profit; individuals.

Estimated Number of Respondents: 24.

Estimated Total Annual Responses: 920.

Frequency of Response: On occasion.

Estimated Total Annual Burden: 867.25 burden hours.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the information collection burden;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: February 4, 2013.

Michele Meyer,

Assistant Director, Legislative & Regulatory Activities Division.

[FR Doc. 2013–02820 Filed 2–7–13; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Information Collection Tools

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 14117, HCTC Registration for Medicare Family Members, and REG–128841–07, Public Approval Guidance for Tax-Exempt Bonds (NPRM).

DATES: Written comments should be received on or before April 9, 2013 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette Lawrence, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224. Please send separate comments for each specific information collection listed below. You must reference the information collection's title, form number, reporting or record-keeping requirement number, and OMB number (if any) in your comment.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the collection tools should be directed to R. Joseph Durbala, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202)622–3634, or through the Internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION: Currently, the IRS is seeking comments concerning the following information collection tools, reporting, and recordkeeping requirements:

(1) *Title:* HCTC Registration for Medicare Family Members.

OMB Number: 1545–2162.

Form Number: 14117.

Abstract: This form will be used by the family members of HCTC eligible individuals under circumstances where the original candidate has died or become divorced from the family member. This form allows family member to begin the HCTC registration process by verifying the family member's eligibility.

Current Actions: There are no changes to the previously approved burden of this existing collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Business and for-profit.

Estimated Number of Respondents: 2,400.

Estimated Time per Respondent: 30 min.

Estimated Total Annual Burden Hours: 1,200.

(2) *Title:* Public Approval Guidance for Tax-Exempt Bonds.

OMB Number: 1545–2185.

Form Number: REG–128841–07.

Abstract: This document contains proposed regulations on the public approval requirements under section 147(f) of the Internal Revenue Code (Code) applicable to tax-exempt private activity bonds issued by State and local governments. The proposed regulations affect State and local governmental issuers of tax-exempt private activity bonds.

Current Actions: There are no changes being made to the revenue procedure at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 2,000.

Estimated Time per Respondent: 1 hr., 18 min.

Estimated Total Annual Reporting Burden hours: 2,600.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate

of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: February 4, 2013.

R. Joseph Durbala,

IRS Reports Clearance Officer.

[FR Doc. 2013–02832 Filed 2–7–13; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Information Collection Tools

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 1024, Application for Recognition of Exemption Under Section 501(a); Form 8038–T, Arbitrage Rebate and Penalty in Lieu of Arbitrage Rebate; the Tip Reporting Alternative Commitment Agreement (TRAC) for Use in the Food and Beverage Industry; the Tip Rate Determination Agreement (TRDA) for industries other than the food and beverage industry and the gaming industry; and Notice 2006–97, Taxation and Reporting of REIT Excess Inclusion Income.

DATES: Written comments should be received on or before April 9, 2013 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224. Please send separate comments for each specific information collection listed below. You must reference the information collection's title, form number, reporting or record-keeping requirement number, and OMB number (if any) in your comment.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the collection tools should be directed to R. Joseph Durbala, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202)622–3634, or through the Internet at *RJoseph.Durbala@irs.gov*.

SUPPLEMENTARY INFORMATION: Currently, the IRS is seeking comments concerning the following information collection tools, reporting, and record-keeping requirements:

(1) *Title:* Application for Recognition of Exemption Under Section 501(a).

OMB Number: 1545–0057.

Form Number: 1024.

Abstract: Organizations seeking exemption from Federal income tax under Internal Revenue Code section 501(a) as an organization described in most paragraphs of section 501(c) must use Form 1024 to apply for exemption. The information collected is used to determine whether the organization qualifies for tax-exempt status.

Current Actions: There are no changes to the previously approved burden of this existing collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Not-for-profit institutions.

Estimated Number of Respondents: 4,718.

Estimated Time Per Respondent: 61 hrs., 47 min.

Estimated Total Annual Burden Hours: 291,542.

(2) *Title:* Arbitrage Rebate and Penalty in Lieu of Arbitrage Rebate.

OMB Number: 1545–1219.

Form Number: 8038–T.

Abstract: Form 8038–T is used by issuers of tax exempt bonds to report and pay the arbitrage rebate and to elect and/or pay various penalties associated with arbitrage bonds. The issuers include state and local governments.

Current Actions: There are no changes being made to the revenue procedure at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: State, local or tribal governments.

Estimated Number of Respondents: 2,500.

Estimated Time Per Respondent: 23 hrs., 10 min.

Estimated Total Annual Reporting Burden hours: 57,900.

(3) *Title:* Tip Reporting Alternative Commitment Agreement (TRAC) for Use in the Food and Beverage Industry.

OMB Number: 1545–1549.

Form Number: N/A.

Abstract: Announcement 2000–22, 2000–19 I.R.B. 987, and Announcement 2001–1, #2001–2 I.R.B. p.277, contain Information required by the Internal Revenue Service in its compliance efforts to assist employers and their employees in understanding and complying with Internal Revenue Code section 6053(a), which requires employees to report all their tips monthly to their employers.

Current Actions: There is no change in the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 41,800.

Estimated Time Per Respondent: 7 hrs., 6 min.

Estimated Total Annual Burden Hours: 296,916.

(4) *Title:* Tip Rate Determination Agreement (TRDA) for industries other than the food and beverage industry and the gaming industry.

OMB Number: 1545–1717.

Form Number: N/A.

Abstract: Announcement 2000–20, 2000–19 I.R.B. 977, and Announcement 2001–1, #2001–2 I.R.B. p.277 contain information required by the Internal Revenue Service in its tax compliance efforts to assist employers and their employees in understanding and complying with Internal Revenue Code section 6053(a), which requires employees to report all their tips monthly to their employers.

Current Actions: There is no change in the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 100.

Estimated Time per Respondent: 18 hrs., 58 min.

Estimated Total Annual Burden Hours: 1,897.

(5) *Title:* Taxation and Reporting of REIT Excess Inclusion Income.

OMB Number: 1545–2036.

Form Number: Notice 2006–97.

Abstract: This notice requires certain REITs, partnerships and other entities that have excess inclusion income to disclose the amount and character of such income allocable to their record interest owners. The record interest owners need the information to properly report and pay taxes on such income.

Current Actions: There is no change in the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 50.

Estimated Time per Respondent: 2 hr.

Estimated Total Annual Burden Hours: 100.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: February 4, 2013.

R. Joseph Durbala,

IRS Reports Clearance Officer.

[FR Doc. 2013–02831 Filed 2–7–13; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0737]

Agency Information Collection (eBenefits Portal) Activity Under OMB Review; Correction

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice; correction.

SUMMARY: The Department of Veterans Affairs (VA) published a collection of information notice in the **Federal Register** on January 31, 2013, that contained an error. The notice incorrectly identified the responsible VA organization. This document corrects that error by removing ''Office of Information and Technology'' and adding, in its place, ''Veterans Benefits Administration''.

FOR FURTHER INFORMATION CONTACT: Crystal Rennie, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, at 202–632–7492.

SUPPLEMENTARY INFORMATION:

Correction.

In FR Doc. 2013–02025, published on January 31, 2013, at 78 FR 6849, make the following correction. On page 6849, in the first column, at the Agency heading, remove ''Office of Information and Technology'' and add, in its place, ''Veterans Benefits Administration''.

Dated: February 5, 2013.

William F. Russo,

Deputy Director, Office of Regulations Policy and Management, Office of General Counsel, Department of Veterans Affairs.

[FR Doc. 2013–02906 Filed 2–7–13; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Rehabilitation Research and Development Service Scientific Merit Review Board, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2, that the subcommittees of the Rehabilitation Research and Development Service Scientific Merit Review Board will meet from 8 a.m. to 5 p.m. on the dates indicated below:

Subcommittee	Date(s)	Location
Aging and Neurodegenerative Disease	February 20, 2013	*VA Central Office.
Rehabilitation Engineering and Prosthetics/Orthotics.	February 20, 2013	Courtyard DC/U.S. Capitol.
Brain Injury: TBI & Stroke	February 20–21, 2013	*VA Central Office.
Musculoskeletal/Orthopedic Rehabilitation	February 20–21, 2013	Paralyzed Veterans of America.
Psychological Health and Social Reintegration	February 20–21, 2013	Paralyzed Veterans of America.
Sensory Systems/Communication	February 26, 2013	Paralyzed Veterans of America.
Regenerative Medicine	February 26–27, 2013	Paralyzed Veterans of America.
Career Development Award Program and Research Career Scientists.	February 26–28, 2013	*VA Central Office.
Spinal Cord Injury	February 28, 2013	*VA Central Office.

The addresses of the meeting sites are:

VA Central Office, 131 M Street NE., Washington, DC 20002 (*Teleconfernce)

Courtyard DC/U.S. Capitol, 1325 2nd Street NE., Washington, DC 20002.

Paralyzed Veterans of America, 801 Eighteenth Street NW., Washington, DC 20006.

The purpose of the Board is to review rehabilitation research and development applications and advise the Director, Rehabilitation Research and Development Service, and the Chief Research and Development Officer on the scientific and technical merit, the mission relevance, and the protection of human and animal subjects.

The subcommittee meetings will be open to the public for approximately one-half hour at the start of each meeting to cover administrative matters and to discuss the general status of the program. The remaining portion of each subcommittee meetings will be closed to the public for the discussion, examination, reference to, and oral review of the research applications and critiques. During the closed potion of each subcommittee meeting, discussion and recommendations will include qualifications of the personnel conducting the studies (the disclosure of which would constitute a clearly unwarranted invasion of personal privacy), as well as research information

(the premature disclosure of which would likely compromise significantly the implementation of proposed agency action regarding such research projects). As provided by subsection 10(d) of Public Law 92–463, as amended by Public Law 94–409, closing the meeting is in accordance with 5 U.S.C. 552b(c)(6) and (9)(B).

No oral or written comments will be accepted from the public for either portion of the meetings. Those who plan to attend the open portion of a subcommittee meeting should contact Tiffany Asqueri, Designated Federal Officer, Rehabilitation Research and Development Service, at Department of Veterans Affairs (10P9R), 810 Vermont Avenue NW., Washington, DC 20420, or email *tiffany.asqueri@va.gov.* For further information, please call Mrs. Asqueri at (202) 443–5757.

Dated: February 4, 2013.

By Direction of the Secretary:

Vivian Drake,

Committee Management Officer.

[FR Doc. 2013–02806 Filed 2–7–13; 8:45 am]

BILLING CODE P

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Part II

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42 CFR Parts 402 and 403
Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 402 and 403

[CMS–5060–F]

RIN 0938–AR33

Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule will require applicable manufacturers of drugs, devices, biologicals, or medical supplies covered by Medicare, Medicaid or the Children's Health Insurance Program (CHIP) to report annually to the Secretary certain payments or transfers of value provided to physicians or teaching hospitals (''covered recipients''). In addition, applicable manufacturers and applicable group purchasing organizations (GPOs) are required to report annually certain physician ownership or investment interests. The Secretary is required to publish applicable manufacturers' and applicable GPOs' submitted payment and ownership information on a public Web site.

DATES: *Effective date:* These regulations are effective on April 9, 2013.

Compliance date: Applicable manufacturers and applicable group purchasing organizations must begin to collect the required data on August 1, 2013 and report the data to CMS by March 31, 2014.

FOR FURTHER INFORMATION CONTACT: Erica Breese, (202) 260–6079.

SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

A. Executive Summary for This Final Rule

1. Purpose

This final rule is necessary to implement the requirements in section 6002 of the Affordable Care Act, which added section 1128G to the Social Security Act (the Act). That provision requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered under title XVIII of the Act (Medicare) or a State plan under title XIX (Medicaid) or XXI of the Act (the Children's Health Insurance Program, or CHIP) to report annually to the Secretary certain payments or other transfers of value to physicians and teaching hospitals. Section 1128G of the Act also requires applicable manufacturers and applicable group purchasing organizations (GPOs) to report certain information regarding the ownership or investment interests held by physicians or the immediate family members of physicians in such entities.

We believe that these provisions of the Act were modeled largely on the recommendations of the Medicare Payment Advisory Commission (MedPAC), which voted in 2009 to recommend Congressional enactment of a new regulatory program. In addition, the Institute of Medicine (IOM) recommended implementing a national disclosure program for payments to health care providers and prescribers in the 2009 report titled, ''Conflict of Interest in Medical Research, Education and Practice.'' Given these recommendations and other information on conflicts of interest that could affect treatment decisions, Congress enacted legislation establishing a national disclosure program with section 6002 of the Affordable Care Act. This final rule provides the implementing requirements for this program.

2. Summary of the Major Provisions

a. Transparency Reports

This rule finalizes requirements for applicable manufacturers to annually report certain payments or other transfers of value to covered recipients. The rule provides definitions of numerous terms, such as applicable manufacturer, and covered drug, device, biological, and medical supply. In addition, the rule also clarifies how applicable manufacturers should report and characterize payments or other transfers of value, including rules for research payments, and indirect payments provided to a covered recipient through a third party. The rule also finalizes which payments or other transfers of value are excluded from the reporting requirements.

In addition, the rule finalizes the requirements for applicable manufacturers and applicable GPOs to annually report information about certain ownership or investment interests held by physicians and the immediate family members of physicians in such entities, as well as payments and other transfers of value to such physicians. The rule details what constitutes an ownership or investment interest for purposes of the reporting requirements, and defines for whom they must be reported. The rule also clarifies the content for the ownership or investment interest report.

b. Report Submission, Correction, and Publication

The rule finalizes the processes and requirements for applicable manufacturers and applicable GPOs to submit their reports to CMS, including the specific data elements required to be included in the reports and the report format. The rule also details the processes for the review, dispute, and correction period when applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors are provided the opportunity to review, dispute, and propose corrections to reported payments or other transfers of value, or ownership or investment interests, attributed to them. In addition, the rule clarifies the information to be included on the publicly available Web site, as well as the usability of the public Web site. Finally, the rule includes details on the processes for reporting and publishing payments or other transfers of value which are eligible for delayed publication.

c. Penalties

The rule includes details regarding the statutorily authorized civil monetary penalties for failure to report payments or other transfers of value, or physician ownership or investment interests, including clarification of the instances when the penalties will be imposed.

d. Annual Report

The rule finalizes the details of the annual reports to Congress and the States.

e. Relation to State Laws

The rule clarifies the statutory requirements for the pre-emption of State laws.

3. Summary of Costs and Benefits

Based on the comments submitted, we anticipate that much of the total estimated burden of this final rule will fall on applicable manufacturers and applicable GPOs. We have estimated that the total cost of these provisions will be approximately $269 million in the first year and $180 million annually thereafter. We have no empirical ability to estimate the monetary benefits of this provision; however, there are nonmonetary benefits, which are difficult to quantify. Increased transparency regarding the extent and nature of relationships between physicians, teaching hospitals, and industry manufacturers will permit patients to make better informed decisions when choosing health care professionals and making treatment decisions, and deter inappropriate

financial relationships which can sometimes lead to increased health care costs. Additionally, increased transparency about the owners and investors in GPOs will allow purchasers to make better informed decisions and identify potential conflicts of interest with ordering physicians.

B. Background

1. Legislative Overview (Statutory Background)

Section 6002 of the Affordable Care Act added section 1128G to the Act, which requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered under Medicare or a State plan under Medicaid or CHIP to report annually to the Secretary certain payments or other transfers of value to physicians and teaching hospitals. Section 1128G of the Act also requires applicable manufacturers and applicable GPOs to report certain information regarding the ownership or investment interests held by physicians or the immediate family members of physicians in such entities.

Specifically, manufacturers of covered drugs, devices, biologicals, and medical supplies (applicable manufacturers) are required to submit on an annual basis the information required in section 1128G(a)(1) of the Act about certain payments or other transfers of value made to physicians and teaching hospitals (collectively called covered recipients) during the course of the preceding calendar year. Similarly, section 1128G(a)(2) of the Act requires applicable manufacturers and applicable GPOs to disclose any ownership or investment interests in such entities held by physicians or their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. Applicable manufacturers must report the required payment and other transfer of value information annually to the Secretary of the Department of Health and Human Services (HHS) (the Secretary) in an electronic format. The statute also provides that applicable manufacturers and applicable GPOs must report annually to the Secretary the required information about physician ownership and investment interests, including information on any payments or other transfers of value provided to physician owners or investors, in an electronic format by the same date. Applicable manufacturers and applicable GPOs are subject to civil monetary penalties (CMPs) for failing to comply with the reporting requirements of the statute. The Secretary is required by statute to publish the reported data on a public Web site. The data must be downloadable, easily searchable, and aggregated. In addition, we must submit annual reports to the Congress and each State summarizing the data reported. Finally, section 1128G of the Act generally preempts State laws that require disclosure of the same type of information by manufacturers.

2. Transparency Overview

We recognize that collaboration among physicians, teaching hospitals, and industry manufacturers contributes to the design and delivery of life-saving drugs and devices and we received many comments supporting this statement. However, as discussed in the proposed rule and in the public comments submitted, payments from manufacturers to physicians and teaching hospitals can also introduce conflicts of interest that may influence research, education, and clinical decision-making in ways that compromise clinical integrity and patient care, and may lead to increased health care costs.

We recognize that disclosure alone is not sufficient to differentiate beneficial financial relationships from those that create conflict of interests or are otherwise improper. Moreover, financial ties alone do not signify an inappropriate relationship. However, transparency will shed light on the nature and extent of relationships, and will hopefully discourage the development of inappropriate relationships and help prevent the increased and potentially unnecessary health care costs that can arise from such conflicts. Given the intricacies of disclosure and the importance of discouraging inappropriate relationships without harming beneficial ones, we have worked closely with stakeholders to better understand the current scope of the interactions among physicians, teaching hospitals, and industry manufacturers. In addition to this feedback, we consulted with the HHS Inspector General, as required by the statute. Our conclusions and interpretations in the preamble are solely for purposes of this regulation and do not apply in other contexts.

II. Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

In the December 19, 2011 proposed rule (76 FR 78742), we solicited public comment on a number of proposals regarding transparency reports and the reporting of physician ownership or investment interests. In response to our solicitation, we received approximately 373 timely public comments. Most of the public comments addressed provisions included in the proposed rule. We received some comments that were outside the scope of the proposed rule and, therefore, will not be addressed in this final rule. Summaries of the public comments that are within the scope of the proposals and our responses to those comments are set forth in the various sections of this final rule under the appropriate headings. In this final rule, we have organized the document by presenting our proposals, summarizing and responding to the public comments for the proposal(s), and describing our final policy.

The following sections outline the agency's directives concerning implementation of section 1128G of the Act, including clarification of the terms and definitions used in the statute, as well as procedures for the submission, review, and publication of the reported data. For terms undefined by the statute, we have provided definitions where appropriate to provide additional clarity, as well as explanations of how we interpret such terms. During the public comment period, we received numerous comments on how to approach and structure the final rule, such as providing additional examples and memorializing intentions in the regulatory text. We appreciate the comments and have endeavored to develop a final rule that allows for reporting flexibility while also providing sufficient detail, clarity, and standardized processes, in order to better ensure the accuracy of the published data. Throughout the final rule, time periods referenced in days are considered to be calendar days, unless otherwise noted.

A. Timing

This final rule has not been published in time for applicable manufacturers and applicable GPOs to begin collecting the information required in section 1128G of the Act on January 1, 2012, as provided in the statute. In the proposed rule, we indicated that we would not require applicable manufacturers and applicable GPOs to begin collecting the required information until after the publication of this final rule. We proposed a preparation period of 90 days. Additionally, we considered requiring the collection of data for part of 2012, to be reported to CMS by the statutory date of March 31, 2013. We also stated that we were considering requiring the collection of data for part of 2012, to be reported to CMS by the statutory date of March 31, 2013, and requested comments on the feasibility of a partial year collection.

Comment: Many commenters were concerned with the length of time applicable manufacturers and applicable GPOs would be given following publication of the final rule before the data collection requirements begin.

A number of these commenters suggested that the reporting requirements begin as quickly as possible following the publication of the final rule, in order to ensure that there is sufficient time for data to be collected for a partial year of 2012. These commenters recommended a 30-day preparation period. Conversely, many other commenters requested that the data collection requirement not begin until January 1, 2013, stating that the data collection requirement for collecting a partial year of data would be difficult and overly burdensome. Other commenters did not address the beginning date for data collection, but instead advocated for a longer preparation period than the proposed 90 days. The majority of these commenters requested an 180-day preparation period, but a few suggested longer, with the longest being 15 months. Some commenters also requested that regardless of the timing, data collection should begin at the beginning of a quarter and also explained that making systems changes during the last quarter of a year would be difficult.

Response: We appreciate these comments and agree that data collection needs to begin as soon as reasonably possible; however, to allow us time to address the important input we received from stakeholders during the rulemaking process, we announced in May 2012 that we would not require the collection of any data before January 1, 2013. We are finalizing that the data collection requirement will begin on August 1, 2013, allowing about an 180-day preparation period. We believe that this is a sufficient amount of time for applicable manufacturers and applicable GPOs to prepare.

Comment: A few commenters requested that CMS modify the reporting requirements for the first year. Some suggested easing the initial burden by phasing in reporting with a higher minimum dollar threshold, while others recommended collecting more data for 2012 by requiring retroactive reporting.

Response: We appreciate these comments, but we do not believe that we have authority to amend the reporting requirements for the first year. In addition, we believe that changing the reporting requirements for a single year would be operationally difficult, since both CMS and applicable manufacturers and applicable GPOs would have to develop systems and then change them after the first year. The statute sets forth the minimum threshold for reportable payments and does not appear to provide any authority for us to change it. We believe that because the threshold is provided in the statute itself, applicable manufacturers were given adequate notice of the threshold amount and should be able to prepare for it. We are also concerned that changing the threshold for 1 year would be confusing to users. With regard to retroactive reporting, we similarly believe that we do not have the authority to require this and will not adopt that approach.

After consideration of the public comments received and given the timing of the final rule, we are establishing that data collection will begin on August 1, 2013 and must be reported to us by March 31, 2014. There will be no retroactive reporting.

B. Transparency Reports

Section 1128G(a) of the Act outlines the transparency reporting requirements and consists of two paragraphs. The first, section 1128G(a)(1) of the Act, outlines the required reports from applicable manufacturers on payments or other transfers of value to covered recipients. The second, section 1128G(a)(2) of the Act, outlines the reporting requirements for applicable manufacturers and applicable GPOs concerning ownership and investment interests of physicians, and their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. While there is some overlap between these submissions, we proposed that these two types of information be reported separately to ensure that the relevant reporting obligations of applicable manufacturers and applicable GPOs are clearly distinguished. We solicited comment on this general approach, but received no comments, so we are finalizing this provision as proposed.

Additionally, we also want to emphasize that compliance with the reporting requirements of section 1128G of the Act does not exempt applicable manufacturers, applicable GPOs, covered recipients, physician owners or investors, immediate family members, other entities, and other persons from any potential liability associated with payments or other transfers of value, or ownership or investment interests (for example, potential liability under the Federal Anti-Kickback statute or the False Claims Act). However, we also want to make clear that the inclusion of a payment or other transfer of value, or ownership or investment interest on the public database does not mean that any of the parties involved were engaged in any wrongdoing or illegal conduct.

1. Reports on Payments and Other Transfers of Value Under Section 1128G(a)(1) of the Act

a. Applicable Manufacturers

While the term applicable manufacturer was defined in section 1128G of the Act, we provided additional clarification in the proposed rule. In this section, we aim to even more clearly define the entities that will be required to report.

(1) Definition of Applicable Manufacturer

In the proposed rule we defined ''applicable manufacturer'' for the purposes of this regulation as an entity that is—

- Engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States; or
- Under common ownership with an entity in the first paragraph of this definition, and which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States.

In defining applicable manufacturer, we interpreted the statutory phrase ''operating'' in the United States, or in a territory, possession, or commonwealth of the United States in section 1128G(e)(2) of the Act, as ''for sale or distribution'' in the United States, or in a territory, possession, or commonwealth of the United States.

Comment: Many commenters expressed concern with CMS's interpretation of the phrase ''applicable manufacturer.'' Specifically, many commenters suggested that the phrase ''for sale or distribution'' is overly broad and would apply to nearly any entity in the world involved in the manufacturing chain or marketing of a covered drug, device, biological, or medical supply (referred to generally for purposes of this rule as a ''covered product'') that is ultimately sold or distributed in the United States, even if such entity has no operations in the United States. These commenters

recommended that CMS retain the statutory language and define the phrase ''operating'' in the United States as having a physical location in the United States or conducting business activities in the United States. Several commenters agreed with and supported the proposed definition.

Response: We appreciate the comments and agree that the proposed definition may have inadvertently captured entities that operate wholly outside the United States, many of which may have little or no interaction with U.S. health care providers. We did not intend to capture foreign entities that may contribute to the manufacturing process of a covered product, but have no business presence in the United States. Accordingly, we have decided to revise the definition by retaining the statutory phrase operating in the United States, which we defined as having a physical location within the United States, or otherwise conducting activities within the United States or in a territory, possession, or commonwealth of the United States. We believe that any manufacturer, foreign or not, which operates in the United States (including by selling a product) must comply with the reporting requirements, regardless of where the product is physically manufactured. Therefore, under this final rule, entities based outside the United States that *do* have operations in the United States are subject to the reporting requirements. Additionally, we note that entities that have operations in the United States are not permitted to circumvent the reporting requirements by making payments to covered recipients indirectly through a foreign entity that has no operations in the United States. Such payments are considered to be made by the entity that is operating in the United States as an indirect payment or other transfer of value and must be reported as such, so long as the entity operating in the United States is aware of the identity of the covered recipients receiving the payments as required for all indirect payments or other transfers of value.

Comment: Many commenters recommended additional limitations on the scope of the definition of applicable manufacturer. A few commenters suggested CMS limit the definition to manufacturers directly involved in manufacturing of the final products, and not entities that supply components and raw materials. In addition, many commenters stated that the definition should not include hospitals or other entities that produce covered products for sale to or use by their own patients only. A few commenters provided similar comments that entities that produce or compound products or tests should be exempt from the definition. For example, many pharmacies compound medications in small batches for individual patients at the direction of a prescribing physician.

Response: We recognize that entities that only manufacture raw materials or components may differ from manufacturers of the final product, and we believe that the statutory framework already treats them differently. The definition of ''applicable manufacturer'' is dependent on the definition of ''covered drug, device, biological or medical supply.'' Raw materials and components often do not meet the definition of covered drug, device, biological, or medical supply because payment is not available for them in their component form under Medicare, Medicaid or CHIP. Entities that only manufacture raw materials or components, which are not themselves covered products, will not be required to report unless they are under common ownership with an applicable manufacturer and assist such manufacturer with the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply. In the event a supplier of raw materials is under common ownership with an applicable manufacturer, it will be subject to the reporting requirements for entities under common ownership, including options for consolidated reporting with the applicable manufacturer.

In addition, we agree with the comments regarding hospitals, pharmacies, and laboratories that produce or manufacture materials and products solely for their own use or use by their patients. We believe that it was not the intent of the statute to include these entities as applicable manufacturers, since they are not listed in the statute as manufacturers. Given these considerations, we have revised the definition of applicable manufacturer to exclude entities such as hospitals, hospital-based pharmacies and laboratories that manufacture a covered product solely for use by or within the entity itself or by an entity's own patients. In addition, the definition of applicable manufacturer does not include pharmacies, including compounding pharmacies, that meet all of the following conditions: (1) Maintain establishments that comply with applicable local laws regulating the practice of pharmacy; (2) regularly engage in dispensing prescription drugs or devices upon prescriptions from licensed practitioners in the course of their professional practice; and (3) do not produce, prepare, propagate, compound, or convert drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail to individual patients.

Comment: Many commenters addressed whether distributors and wholesalers, including repackagers, relabelers, and kit assemblers, met the definition of applicable manufacturer. These entities were not specifically addressed in the proposed rule other than the recognition that there are other definitions of ''manufacture,'' ''manufacturer'' and ''manufacturing'' with which industry may be familiar (such as those in 21 CFR 207.3, 21 CFR 210.3(b)(12), 21 CFR 820.3(o), and 42 U.S.C. 1396r–8(k)(5)). The commenters represented both sides—some advocated that these types of entities meet the definition, while others advocated that they do not. Some commenters noted that distributors and wholesalers purchase and often take the title to covered products and then sell them to providers. The distributor may or may not rebrand or repackage the product before resale. Commenters on both sides referred to other definitions of ''manufacturer'' and ''manufacture'' both in the Affordable Care Act and elsewhere, some of which specifically reference distributors and some of which did not, similar to the statutory definition in section 1128G(e)(9) of the Act. The advocates for including distributors and wholesalers state that because these entities are involved in ''preparation'' and ''propagation'' of covered products, they should be included based on the statutory definition. Conversely, other commenters stated that distributors and wholesalers stock multiple competing products, so they do not try to sway purchasing decisions in the same way as a manufacturer.

Response: We agree that distributors and wholesalers (which include repackagers, relabelers, and kit assemblers) that hold the title to a covered drug, device, biological or medical supply meet the definition of an applicable manufacturer for the purpose of this rule. We believe that distributors that hold the title to a covered product are similar to applicable manufacturers since both hold title to the product at some point in the production and distribution cycle. These entities will be subject to the same requirements as all other applicable manufacturers, as described in more detail in this section. Wholesalers or distributors that do *not*

hold the title of a covered product will not be subject to the reporting requirements, unless they are under common ownership with an applicable manufacturer and provide assistance or support with respect to a covered drug, device, biological, or medical supply. Finally, an applicable manufacturer that has product(s) with titles held by distributors does not need to report payments or other transfers of value made by the distributor or wholesaler to covered recipients, since these will be reported by the distributor or wholesaler. However, in the event that the applicable manufacturer makes payments or other transfers of value related to the product independently from the distributor or wholesaler (or through the distributor or wholesaler as a third party), then the applicable manufacturer would have to report these payments or other transfers of value.

(2) Limitations to the Definition of Applicable Manufacturer

In the preamble to the proposed rule, we clarified that the applicable manufacturer definition included entities that hold Food and Drug Administration (FDA) approval, licensure, or clearance for a covered drug, device, biological, or medical supply, even if they contract out the actual physical manufacturing of the product to another entity. We interpreted these entities as being ''engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply.'' However, we did not address whether the entity manufacturing the product under contract is an applicable manufacturer. We also proposed that any manufacturer that meets the definition of applicable manufacturer by manufacturing at least one covered drug, device, biological or medical supply (as defined later in this section) would be considered an applicable manufacturer, even though it may also manufacture products that do not fall within that category.

Comment: A few commenters requested clarification on the reporting requirements for situations when the license-holder is not the manufacturer or the manufacturing process is contracted out. These commenters recommended that if an entity, which manufactures a covered product under contract, but does not market or distribute the product and is not an applicable manufacturer otherwise, then the entity does not meet the definition and does not need to report.

Response: We agree that additional clarification is necessary, although we recognize that it is difficult to anticipate all potential manufacturing arrangements. In general, we believe that our proposed position to require reporting by an entity that holds an FDA approval, licensure, or clearance for a covered product is appropriate. Such entities are clearly ''engaged in the production, preparation, propagation, compounding, or conversion'' of a covered product. We did not receive any comments on this and are finalizing it as proposed. For the contracted entity conducting the actual manufacturing, we believe that these entities fit into the definition of applicable manufacturer, since they are actually manufacturing a covered product and clearly are ''engaged in the production, preparation, propagation, compounding, or conversion'' of a product. Therefore, we are finalizing that entities that manufacture any covered product are applicable manufacturers, even if the manufacturer does not hold the FDA approval, licensure, or clearance. While we recognize that such entities do not necessarily market the product, we believe it is clear that they do manufacture it. However, we also understand that these manufacturers' business model may not be focused on covered products. Therefore, if an applicable manufacturer does not manufacture a covered drug, device, biological, or medical supply except pursuant to a written agreement to manufacture the covered product for another entity, does not hold the FDA approval, licensure or clearance for the product, *and* is not involved in the sale, marketing or distribution of the product, then the manufacturer is only required to report payments or other transfers of value *related to the covered product.* This is described in the regulatory text at § 403.904(b)(4). If an applicable manufacturer has this business arrangement for some products and also manufactures at least one covered product that does not meet these criteria, then the applicable manufacturer must report all payments or other transfers of value subject to the reporting requirements. We believe that this is consistent with our treatment of other manufacturers with business models that are not focused on covered products, as discussed in more detail in this section. Finally, no payment or other transfer of value should be reported more than one time by a single entity.

Comment: Several commenters also discussed CMS's proposed decision to require applicable manufacturers to report all payments or transfers of value to covered recipients rather than only payments related to covered drugs, devices, biologicals, and medical supplies. While a few commenters supported this proposal, others did not. Entities and organizations with only a small number of covered products believed that reporting all payments would be overly burdensome and recommended limiting the definition to manufacturers that obtain a certain percentage (generally 5 or 10 percent) of their sales or revenues from covered products.

Response: We stand by our decision to require reporting of all payments or transfers of value to covered recipients rather than only payments related to covered drugs, devices, biologicals, and medical supplies and discuss this decision more fully in section II.B.1.b of this final rule. We do not believe that all payments or other transfers of value are related to particular covered products, so we do not want an applicable manufacturer to avoid reporting by representing certain payments or other transfers of value to covered recipients as being unrelated to covered products.

However, we are sensitive to applicable manufacturers whose primary business focus is not the production of covered drugs, devices, biological or medical supplies, but may still produce one or a few covered products. We recognize that since so few of their products are covered, many of their competitors will not be subject to the reporting requirements, providing the competitors with a potential competitive advantage. Despite this recognition, we also do not believe that these entities should be exempt from all reporting, since other manufacturers of the same covered products with a different business model would be subject to reporting. We recognize that these applicable manufacturers could also classify payments or other transfers of value as unrelated to a covered drug, device, biological or medical supply in order to try to avoid the reporting requirements; however, we believe the burden on these applicable manufacturers of reporting all interactions related to all products (not just covered drugs, devices, biologicals, or medical supplies) outweighs this concern. Therefore, we have clarified the agency's position in § 403.904(b)(1) to allow applicable manufacturers with less than 10 percent of total (gross) revenues from covered drugs, devices, biologicals or medical supplies during the previous fiscal year to report only payments or other transfers of value specifically related to covered drugs, devices, biologicals or medical supplies.

The 10-percent threshold should be calculated based on the company's total (gross) annual revenue. Applicable manufacturers with less than 10 percent of total (gross) revenue from covered products during the previous year that have payments or other transfers of value to report must register with CMS and must attest that less than 10 percent of total (gross) revenues are from covered products, along with their attestation of the submitted data. We selected a 10-percent threshold based on the public comments that we received suggesting a range from 5 to 10 percent; we chose the higher percentage in order to reduce the reporting burden on a greater number of entities.

Comment: A few commenters also requested additional clarification on when an entity with no covered products becomes an applicable manufacturer because payment becomes available for one of the company's products under Medicare, Medicaid or CHIP (for example, because a manufacturer's only product received FDA approval). Most of the commenters simply requested clarification, since this was not addressed in the proposed rule. However, a commenter suggested that CMS should allow new applicable manufacturers a grace period (for example, 180 days) to allow the manufacturer time to prepare to comply with the data collection requirements.

Response: We agree that we should provide clarification on when a product becomes ''covered'' and, thus, when an applicable manufacturer who did not previously have any other covered products becomes subject to the data collection and reporting requirements under this rule. We will allow the applicable manufacturer a grace period of 180 days following a product becoming ''covered'' to begin complying with the data collection and reporting requirements. We believe this is appropriate because it is the same preparation period allowed after the publication of the final rule, allowing all new applicable manufacturers the same time to prepare for complying with the data collection and reporting requirements.

(3) Common Ownership

The definition of applicable manufacturer includes entities under common ownership with an applicable manufacturer. We proposed to define ''common ownership'' as when the same individual, individuals, entity, or entities, directly or indirectly, own any portion of two or more entities. This would apply to a range of corporate arrangements, including, but not limited to, parent companies and subsidiaries and brother/sister corporations. In addition, we also included an alternate interpretation that would limit the common ownership definition to circumstances where the same individual, individuals, entity, or entities own 5 percent or more of total ownership in two or more entities. This would be subject to the same requirements as the definition described previously, but would only apply to common interests of 5 percent or more.

Regarding how applicable manufacturers under common ownership will submit reports, we proposed that if two or more entities individually met the proposed definition of an applicable manufacturer under paragraph (1) of the definition, the entities should report separately under section 1128G of the Act. However, if only one company under common ownership met the proposed definition of applicable manufacturer under paragraph (1) of the proposed definition, and the other company is required to report under paragraph (2) of the definition, then the affected entities can choose whether or not to report together. Additionally, we proposed that a payment or other transfer of value provided to a covered recipient in accordance with a joint venture or other cooperative agreement between two or more applicable manufacturers must be reported in the name of the applicable manufacturer that actually furnished the payment or other transfer of value to the covered recipient, unless the terms of a written agreement between the applicable manufacturers specifically require otherwise, so long as the agreement requires that all payments or other transfers of value in accordance with the arrangement are reported by one of the applicable manufacturers.

Comment: Many commenters did not support the agency's definition of common ownership. These commenters generally recommended that a threshold greater than the proposed alternative of 5 percent be applied to determine common ownership. The commenters that support a higher threshold generally advocated for a ''common control'' standard, which is traditionally a greater ownership percentage of 50 to 80 percent, rather than an affiliate status, which is generally around 5 percent. Conversely, some commenters supported the proposed definition, as well as the 5 percent alternative.

Response: We appreciate the comments and have decided to finalize the 5-percent ownership threshold for common ownership. We recognize that this is a lower threshold than many of the commenters recommended; however, we believe this is appropriate. We believe that had Congress intended to establish a ''common control'' standard, it would have used that term, rather than ''common ownership.'' Similarly, a 5-percent threshold for common ownership is used elsewhere in the Act, in other CMS regulations, and is one with which entities are familiar. For example, section 1124(a)(3) of the Act defines the term ''person with an ownership or control interest,'' in part, as a person who has a direct or indirect ownership interest in an entity of at least 5 percent. We also believe that clarifying when an entity under common ownership has to report (as explained in this section) will help reduce the number of entities under common ownership reporting.

Comment: Many commenters also requested additional clarification on how the agency was interpreting ''assistance and support'' for entities under common ownership, since only entities under common ownership which provide ''assistance and support'' for the listed manufacturing activities need to report. These commenters varied in their suggestions, but most advocated a narrow interpretation, such as only those involved in sales and marketing or those entities integral or necessary to the manufacturing process. In addition, some commenters questioned whether separate operating divisions, which are not related to covered products, such as the animal health division or over-the-counter drugs division, need to report. The commenters advocated that reporting of these divisions would be confusing, since they are unrelated to covered products.

Response: We appreciate these comments and agree that we should provide greater clarification to help identify the entities under common ownership which are required to report. We define ''assistance and support'' as being necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered product. For example, an entity under common ownership which produces the active ingredient for a covered drug and provides it to the applicable manufacturer for inclusion in the final product would be considered necessary to the manufacturing of that product, since the applicable manufacturer could not produce the drug without the active ingredient. Conversely, an entity under common ownership that only aids the applicable manufacturer with human resources administrative functions would not be deemed necessary or integral to the production, preparation, propagation,

compounding, conversion, marketing, promotion, sale, or distribution of covered products, since human resources functions are not directly involved with any of these manufacturing processes.

In general, we believe that all payments or other transfers of value related to covered products should be reported, but that we should minimize the reporting of payments or other transfers of value unrelated to covered products. The final rule does not require entities under common ownership to report when they are not necessary or integral to manufacturing, and are not applicable manufacturers in and of themselves. However, an indirect payment or other transfer of value made to a covered recipient through an entity under common ownership that is not necessary or integral to the manufacturing process must still be reported as required for indirect payments or other transfers of value. In addition, we believe that entities under common ownership that are necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered product should not have to report all payments or other transfers of value that the entities provide to covered recipients, and § 403.904(b)(2) of this final rule states that they only need to report payments or other transfers of value that are related to covered products.

Finally, with regard to applicable manufacturers that have separate operating divisions that only produce non-covered products and do not meet the definition of providing ''assistance and support,'' we believe that such divisions only need to report payments or other transfers of value that are related to a covered drug, device, biological or medical supply as stated in § 403.904(b)(3). We believe that the vast majority of payments or other transfers of value will not be related to covered products. To prevent applicable manufacturers from diverting payments through these divisions in order to avoid the reporting requirements, we are finalizing that all payments or other transfers of value made by these divisions that are related to covered products must be reported. This includes payments or other transfers of value made directly by the operating division, as well as payments or other transfers of value made indirectly by the applicable manufacturer through the separate operating division, as the latter payments are required to be reported as indirect payments or other transfers of value.

Comment: Many commenters advocated that CMS should allow entities more flexibility to submit consolidated reports, regardless of whether an entity meets the definition of applicable manufacturer under paragraph 1 or 2 of the proposed definition and at the company or operating division level. These commenters explained that manufacturers may have complicated corporate structures and reporting systems and suggested that the agency provide additional flexibility in reporting. Additionally, the commenters noted that consumers may not be familiar with the names of manufacturers' smaller divisions and, therefore, publication of the data under the names of the smaller divisions could limit the usefulness of the published data to consumers. Other commenters agreed with increased flexibility, but advocated that the reports should clearly state what entities are included in the report, including reporting which payments were made by which entity.

Response: We agree that entities should have more flexibility to report together or separately. Therefore, we clarified in § 403.908(d) that applicable manufacturers under paragraph 1 of the definition that are under common ownership with separate entities that are also applicable manufacturers under paragraph 1 may, but are not required to, file a consolidated report for all of the entities. Additionally, as we stated in the proposed rule, applicable manufacturers under paragraph 1 of the definition of applicable manufacturer and an entity (or entities) under common ownership with such manufacturer under paragraph 2 of the definition also may, but are not required to, file a consolidated report. We believe that this will make reporting less burdensome to entities and will provide more clarity to consumers. However, we are concerned that it will not be clear to CMS or consumers which companies are under common ownership and are either reporting together or separately. Therefore, if multiple applicable manufacturers (under paragraph 1 and/or 2 of the definition) submit a consolidated report, we are requiring that the report must provide information specified by CMS to identify each applicable manufacturer and entity (or entities) under common ownership that the report covers. Additionally, applicable manufacturers submitting consolidated reports must specify on an individual payment line which entity made which discrete payment or other transfer of value. We believe this method is more useful for consumers since it clarifies the specific entity making the payment. We also believe that this method provides significantly more clarity for covered recipients when reviewing their payments or other transfers of value, allowing them to better review the information submitted on their behalf. Regardless of whether applicable manufacturers file separate or consolidated reports, § 403.908(d)(1)(iv) and (d)(2)(ii) clarify that in no case shall a single payment or other transfer of value be reported more than once by multiple applicable manufacturers (under common ownership or not). Each transaction between an applicable manufacturer and a covered recipient must be reported only one time. Also, to support our ability to improve identity and data matching, regardless of whether applicable manufacturers file separate or consolidated reports, all covered recipients included in the report must be individually, uniquely and consistently identified. The same individual, if present on multiple payment lines within the same report, must have the same unique identifiers for all occurrences within the report. For example, the same name and National Provider Identifier (NPI) (as required to be reported in this final rule) should be used consistently for all payment lines and any subsequent updates for the same individual. Finally, we did not receive any comments on our proposed reporting method for joint ventures and co-promotions, so we have finalized these provisions as proposed, which required reporting by the applicable manufacturer that actually made the payment or other transfer of value (unless decided by the parties to report differently) and that the payment or other transfer of value was only reported once.

In sum, after consideration of the public comments received, we are revising the interpretation of what it means that an entity is ''operating in'' the United States. We are finalizing the position that applicable manufacturers must report all payments or other transfers of value, but clarifying that manufacturers with less than 10 percent of their gross revenue coming from covered products only have to report payments related to covered products. In addition, we are also finalizing the definition of common ownership to require a threshold of 5 percent or more common ownership interest and providing additional clarification on the requirements for reporting by entities under common ownership. Finally, we are allowing additional flexibility for

applicable manufacturers (under paragraph 1 and/or 2 of the definition) to report separately or together depending on their internal structure.

b. Covered Drug, Device, Biological, or Medical Supply

The data collection and reporting requirements are limited to applicable manufacturers of a ''covered drug, device, biological, or medical supply.'' The phrase ''covered drug, device, biological, or medical supply'' is defined in section 1128G(e)(5) of the Act as any drug, biological product, device, or medical supply for which payment is ''available'' under Medicare, Medicaid, or CHIP. Because there are numerous payment mechanisms in Medicare, Medicaid and CHIP, we proposed that drugs, devices, biologicals, or medical supplies for which payment is available through a composite payment rate, as well as those reimbursed separately, are considered to be covered products under section 1128G of the Act. We were particularly concerned about inadvertently excluding items, such as implantable devices, for which payment may be available only as part of a bundled payment.

We proposed to define ''covered drug, device, biological, or medical supply'' as: any drug, device, biological, or medical supply for which payment is available under Title XVIII of the Act or under a State plan under Title XIX or XXI (or a waiver of such plan), either separately, as part of a fee schedule payment, or as part of a composite payment rate (for example, the hospital inpatient prospective payment system or the hospital outpatient prospective payment system).

The proposed definition included two exceptions to limit the entities reporting. We proposed to limit drugs and biologicals in the definition of ''covered drug, device, biological, and medical supply,'' to drugs and biologicals that, by law, require a prescription to be dispensed, thus excluding drugs and biologicals that are considered ''over-the-counter'' (OTC). Similarly, we proposed an additional limitation to the definition as it pertains to devices and medical supplies, which would limit them to those devices (including medical supplies that are devices) that, by law, require premarket approval by or notification to FDA. This would exclude many Class I devices and certain Class II devices, which are exempt from premarket notification requirements under 21 U.S.C. 360(l) or (m), such as tongue depressors and elastic bandages.

Beyond coverage, the proposed rule also discussed what payments or other transfers of value must be reported. In the proposed rule, we specifically stated that manufacturers who manufacture both non-covered products (such as OTC drugs) *and* at least one product that falls within the definition of a covered drug, device, biological or medical supply would be required to report *all* payments or transfers of value to covered recipients required by section 1128G of the Act (whether or not associated with a covered drug, device, biological or medical supply).

Comment: Many commenters inquired about the definition of covered drug, device, biological, or medical supply. Many commenters supported the proposed definition, particularly the proposed limitations, which did not receive any opposition. However, a few commenters sought clarification on how the two parts of the definition work together. These commenters sought clarification, for example, on whether a drug or biological that requires a prescription to be dispensed or a device that requires premarket approval or clearance, but for which payment is not available under Medicare, Medicaid or CHIP, would be a covered product.

Response: We are pleased with the support for the proposed definition, including the limitations, and have finalized them. In addition, we agree with the commenters regarding a need for clarification concerning the relationship between the parts of the definition. We had intended the interpretation of the definition to require that a product must meet both parts of the definition in order to be considered covered. In order to make this more clear, we have revised the definition to clearly state that a covered drug, device, biological or medical supply is one for which payment is available under Medicare, Medicaid or CHIP *and* which, requires a prescription to be dispensed (in the case of a drug or biological) or premarket approval by or notification to the FDA (in the case of a device or a medical supply that is a device). For example, a device which is of a type that requires premarket notification, but for which payment is not available under Medicare, Medicaid, or CHIP, would not be a covered device under the program. Finally, we do not intend to capture *all* items that require FDA premarket approval or premarket notification and for which payment is available under Medicare, Medicaid, or CHIP; rather, we only intend to include items that meet these criteria *and* that are devices (or medical supplies that are devices). For example, the definition is not intended to include products that require premarket approval or premarket notification, but that are regulated by the FDA solely as a food.

Comment: Many commenters requested additional clarification and details concerning the meaning of payment being ''available'' under Medicare, Medicaid or CHIP. Some commenters inquired whether the availability of payment referred only to those items that have been approved or cleared by FDA. Other commenters suggested that the definition should only include payments for products which are reimbursed separately, and not through a bundled payment. Finally, a few commenters inquired whether the proposed definition referred to payment availability on a single basis (for example, as a result of an appeal) or if payment was regularly available.

Response: We agree with the comments that additional clarification of the meaning of ''availability'' of payment would be useful. The statute provides that in order to be a covered product, payment must be available under Medicare, Medicaid or CHIP. While the statute does not discuss FDA approval, clearance or notification, most products for which payment is available under Medicare, Medicaid or CHIP will have received FDA approval or clearance. However, we note that there may be exceptions. For example, payment may be available under Medicare for certain investigative devices that receive an investigational device exemption (IDE) from the FDA and are classified as a Category B device, in accordance with 42 CFR part 405 Subpart B. In addition, payment may be available under Medicaid for certain drug products described in section 1927(k)(2) of the Act, that have not been approved by the FDA, but were commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 (or which are identical, similar, or related within the meaning of 21 CFR 310.6(b)(1) to such drugs) *and* have not been the subject of a final determination by the Secretary that they are a ''new drug.'' While we understand that a bright line test would be useful, limiting covered products to those that have received FDA approval or clearance (or for which notification has been provided to the FDA) would not be comprehensive. We believe that manufacturers are generally aware when payment is available for their drugs, devices, biologicals, or medical supplies under a Federal health care program.

In addition, we do not agree with the suggestions to interpret payment availability as being limited to those provided separately, rather than through a bundled payment. We recognize that

it is not always clear whether a product is paid through a bundle, making it difficult to establish whether payment is available. We also recognize that this expands the number of products meeting the definition of covered drug, device, biological or medical supply. However, bundled payments constitute a significant portion of Medicare reimbursement and excluding products that are reimbursed only as part of bundled payments would exclude manufacturers of products who have historically had significant relationships with physicians and teaching hospitals. For example, we believe it would be inappropriate to exclude implanted devices that are reimbursed through the hospital inpatient prospective payment system (IPPS) or the outpatient prospective payment system (OPPS), as well as chronic kidney disease drugs and products reimbursed through the end stage renal disease (ESRD) bundled payment system. As a result, the final rule adopts the proposal to include products which are reimbursed separately or as part of a bundled payment. We note that because there was some confusion about the phrase ''composite payment rate'' in the proposed rule, we have replaced it with the phrase ''bundled payment'' and continue to interpret that as meaning IPPS, OPPS, and other prospective payment systems.

Comment: Many commenters also requested clarification on what products constituted a device or medical supply. The proposed rule did not define these terms, so commenters provided recommendations for ways to clarify the terms, such as limiting them to product classes or providing definitions. Additionally, commenters questioned whether specific products would or would not be considered a ''device'' or ''medical supply'' for the purposes of the reporting requirements.

Response: We appreciate the comments and note that covered devices and medical supplies are limited to those devices and medical supplies for which payment is available under Medicare, Medicaid or CHIP, and are of the type that require premarket notification to or premarket approval by the FDA. We believe that this provides applicable manufacturers with a clear sense of the devices and medical supplies that constitute covered devices and medicals supplies, as well as those that do not. For example, FDA defines the devices (including certain medical supplies) that are exempted from the premarket notification requirements. This information can be found in 21 CFR parts 862 through 892 and is publicly available on the FDA's Web site.[1]

Comment: A few commenters suggested that reporting on all payments or other transfers of value, including those related to products under development, is too broad. These commenters recommended that only payments or other transfers of value related to covered products should be reported. Similarly, other commenters requested that payments or other transfers of value for certain products, such as veterinary drugs, be excluded since the relationships related to such products are not intended to be included by the statute.

Response: As noted previously, we are finalizing the proposal that, in most circumstances, applicable manufacturers must report payments or other transfers of value to covered recipients regardless of whether they are related to a covered product. We believe that not all payments or other transfers of value will be related to specific drugs, devices, biologicals, or medical supplies, but they nevertheless represent a financial relationship between an applicable manufacturer and a covered recipient that has the potential to affect medical judgment and must be reported under the requirements in section 1128G of the Act. Additionally, we are concerned that limiting the reporting requirements to payments or other transfers of value related to covered products would create loopholes that would allow entities to avoid reporting of certain payments or other transfers of value. However, we do understand that payments related to products that will never become covered by Medicare, Medicaid or CHIP (such as animal health products) may unnecessarily increase the scope of reporting. Therefore, we have limited the reporting requirements to address this situation, as well as other situations described previously in the discussion of the limitations to the definition of ''applicable manufacturer,'' where requiring an applicable manufacturer to report payments related to non-covered products would be unnecessarily burdensome and not particularly useful to the public. We are finalizing that separate divisions that manufacture only non-covered products do not need to report payments or other transfers of values unless the payments or other transfers of value are in fact related to covered products (see the applicable manufacturer and payments or other transfers of value sections of this final rule). Similarly, we do not intend to capture payments made to a veterinary school that may be associated with a teaching hospital.

[1] List of exempt products: *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm* .

c. Covered Recipients

Under section 1128G(a)(1) of the Act, applicable manufacturers are required to disclose certain payments or other transfers of value made to covered recipients, or to entities or individuals at the request of, or designated on behalf of, a covered recipient. Section 1128G(e)(6) of the Act defines ''covered recipient'' as: (1) a physician, other than a physician who is an employee of an applicable manufacturer; or (2) a teaching hospital. As required by section 1128G(e)(11) of the Act, we proposed to define ''physician'' as having the meaning set forth in section 1861(r) of the Act, which includes doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and chiropractors, who are legally authorized to practice by the State in which they practice.

The statute excludes from the definition of covered recipient a physician who is an employee of the applicable manufacturer, as defined in section 1877(h)(2) of the Act. Section 1877(h)(2) defines ''employee'' as an individual who would be considered to be an employee of an entity under the usual common law rules applicable in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986). We note that these common law rules are discussed in 20 CFR 404.1007 and 26 CFR 31.3121(d) through 1(c).

Finally, we proposed to define the term ''teaching hospital'' by linking it to Medicare graduate medical education (GME). The proposed rule defined teaching hospital as any institution that received payments under section 1886(d)(5)(B) of the Act (indirect medical education (IME)); section 1886(h) of the Act (direct GME); or section 1886(s) of the Act (psychiatric hospital IME) during the most recent year for which such information is available.

Comment: Many commenters recommended changes to the proposed definition of physician. Some commenters requested that CMS expand the definition of physician to include other entities with prescribing privileges. Other commenters inquired about whether residents would be considered physicians. Some commenters requested that the definition exclude physicians who are not actively engaged in (or who do not

''perform'') the practice of medicine, which would include physicians not acting solely within their role as a physician, as well as medical researchers. They refer to the phrase in the statutory definition that a physician is an individual licensed in the State ''in which he performs such function or action.'' Other commenters recommended that the reporting requirements should be limited to physicians enrolled in Medicare, Medicaid or CHIP, on the basis of recent reimbursement or expected reimbursement. Finally, a few commenters recommended that CMS establish an ''opt-out'' function for physicians to declare that they have opted out, and no payments would appear on the public Web site attributed to them.

Response: We appreciate the comments, but we will not expand the definition to include other provider types nor will we limit the definition to exclude those clearly intended in the statutory definition. The statute defines the term ''physician'' as having the same meaning as in section 1861(r) of the Act. We recognize that, as a result, we will not be able to fully capture financial relationships between industry and prescribers, specifically non-physician prescribers such as nurse practitioners. However, to the extent that applicable manufacturers make payments or other transfers of value to non-physician prescribers to be passed through to a physician, they would be indirect payments to the physician and would have to be reported under the name of the physician.

Additionally, we believe that the definition hinges on whether a physician is ''legally authorized'' to practice, so all physicians (including all providers types listed in the statutory definition) that have a current license to practice will be considered covered recipients. By holding a current license to practice, the physician is legally authorized to practice regardless of the extent to which they do so.

Payments or other transfers of value to residents (including residents in medicine, osteopathy, dentistry, podiatry, optometry and chiropractic) will not be required to be reported for purposes of this regulation. We recognize that some States require or allow residents to obtain licenses to practice, whereas other States do not require or allow residents to obtain them. We do not want to treat residents differently depending on their State of residency by requiring reporting on payments to residents in only those States that require or allow residents to have a license. Moreover, we believe it will be difficult for us to accurately identify residents and ensure that payments or other transfers of value are attributed across applicable manufacturers appropriately because many of them do not have a NPI and/or State professional license number (used for physician identification, discussed later in this section). Due to the operational and data accuracy concerns regarding aggregation of payments or other transfers of value to residents, many of whom have neither an NPI nor a State professional license number, applicable manufacturers will not be required to report such payments or other transfers of value.

With regard to the comment that the term ''physician'' should be limited to those enrolled in Medicare, we believe such an interpretation would be contrary to the language of the statute. In contrast to the statutory requirement that products are limited to those for which payment is available under Medicare, Medicaid or CHIP, the statute did not indicate that physician covered recipients be limited to those enrolled in Medicare, Medicaid or CHIP.

Finally, while we appreciate the interest in allowing physicians the opportunity to ''opt-out'' of the reporting requirements, we do not believe it would be possible to implement a system of this kind. We believe it would be overly burdensome for both CMS and applicable manufacturers to track who has opted out and ensure that no payments or other transfers of value are made to those individuals. Additionally, we would need to create a system to reconcile any payments reported as having been made to physicians stating that they have opted out. We believe that a physician who wants to opt out should simply refuse all payments or other transfers of value from manufacturers, and will, accordingly, not be included on the public Web site (unless they hold ownership or investment interests in an applicable manufacturer or applicable GPO).

Comment: Many commenters addressed the exclusion for employees of applicable manufacturers from the definition of physician covered recipient. A few commenters recommended revising the definition to ensure that only ''bona fide'' employee relationships are excluded from reporting, similar to the language in the employee exception in the Anti-Kickback Statute in section 1128(b)(3)(B) of the Act and the corresponding HHS OIG regulation at 42 CFR 1001.952(i). Other commenters questioned whether employees of agents of the applicable manufacturer would be included in the exception. The commenters also noted that the language in the proposed rule indicated that the exception included physicians employed by *an* applicable manufacturer, so it was not limited to employees of the applicable manufacturer making and reporting the payment or other transfer of value. In addition to these more general definitional comments, we also received numerous comments recommending other situations (such as physicians who serve as medical directors or retirees) that should be included in the employee exception.

Response: We appreciate the comments and have clarified the definition of covered recipient to ensure that only bona fide employment relationships are included in the employee exclusion. We are concerned that in the absence of this clarification, applicable manufacturers could circumvent the reporting requirements by styling a physician as an ''employee'' and not reporting payments made to such a physician. Additionally, we did not intend to allow the exception for employees to include physician employees at any applicable manufacturer, rather than only the reporting applicable manufacturer itself. The proposed rule incorrectly quoted the statute, which in section 1128G(e)(6)(B) of the Act states that the term covered recipient ''does not include a physician who is an employee of *the* applicable manufacturer.'' For the final rule, we have reverted to the statutory language. Additionally, regarding employees of agents of the applicable manufacturer, we do not intend these individuals to be included in the exception, since they are not employees of the applicable manufacturer. However, as discussed in the section on indirect payments (section II.B.1.k of this final rule), we do not believe that payments or other transfers of value to legal agents of an applicable manufacturer that happen to have physicians on staff constitutes a payment or other transfer of value for the purposes of this rule.

We appreciate the comments regarding other situations that commenters would like to see included in the employee exclusion, such as an applicable manufacturer's board members and medical directors. However, we believe that whether such individuals fall within the statutory definition of employee in section 1877(h)(2) of the Act, which defines employee by referencing common law rules used to determine the employer-employee relationship for Internal Revenue Service purposes, will require

a case-specific analysis. Therefore, we are not able to adopt a bright-line policy that all board members or medical directors are (or are not) bona fide employees for purposes of the reporting exclusion.

Similarly, with regard to the comments suggesting that prospective employees and retirees should treated as employees for purposes of being excluded from the reporting requirements, we believe that whether such individuals fall within the statutory definition of employee in section 1877(h)(2) of the Act will require a case-specific analysis. Therefore, we are unable to state that payments to such physicians, such as recruiting costs paid to prospective employees, do not need to be reported.

Comment: We received significant support for our proposed definition of teaching hospital. However, some commenters recommended that CMS clarify that payments or other transfers of value to non-healthcare departments at universities affiliated with teaching hospitals should not be included in the reporting requirements.

Response: We have decided to finalize the proposed definition. As explained in the proposed rule, we recognize that this definition may not capture hospitals with accredited medical residency programs that do not receive IME or direct GME payments; however, we are unable to include these hospitals since we cannot readily identify them based on Medicare payment data. Finally, we do agree; payments to non-healthcare departments of universities affiliated with teaching hospitals should not be included in reporting requirements. However, any payments or other transfers of value made through these departments to a covered recipient as indirect payments or other transfers of value must be reported as required for indirect payments.

d. Identification of Covered Recipients

In order to accurately identify and distinguish covered recipients, section 1128G(a)(1) of the Act requires that applicable manufacturers report the covered recipient's name and business address, and for physician covered recipients, the physician's NPI, and specialty. The collection of this information is necessary for applicable manufacturers, in order to distinguish individual covered recipients when reporting to CMS, and for CMS, in order to be able to aggregate the data. This section outlines the comments received regarding identification of both physician and teaching hospital covered recipients.

(1) Identification of Physicians

Section 1128G of the Act requires that applicable manufacturers report a physician covered recipient's name, business address, NPI and specialty. This information will be used to distinguish physicians and allow us to match physicians across applicable manufacturers. We proposed that applicable manufacturers use the National Plan & Provider Enumeration System (NPPES), which we currently maintain and update on the public Web site, to assist with identifying physician covered recipients. The NPPES Web site includes a database of physician NPIs and has an NPI Registry function that allows applicable manufacturers to look up individual physician's NPIs.[2] The full database can be downloaded from the CMS Web site.[3] We proposed that if the physician NPI was not available in NPPES, the applicable manufacturer would be responsible for obtaining the physician's individual NPI directly from the physician, if the physician has an NPI. Other than NPI, in the proposed rule, we considered whether we should require, under the discretion granted in section 1128G(a)(1)(A)(viii) of the Act, that applicable manufacturers report another unique identifier, such as State professional license number, for physicians who are identified, but do not have an NPI.

Comment: A number of commenters provided input on the processes and requirements for applicable manufacturers to report the NPI for a physician. Some commenters noted that reporting a physician covered recipient's NPI is complicated, since not all physicians have an NPI and manufacturers typically do not collect such information. Additionally, a few commenters did not support the requirement that applicable manufacturers must obtain an NPI from a physician, if it was not readily available in the NPPES database. They explained it would be difficult to obtain and questioned how an applicable manufacturer would really know if a physician did not have an NPI. Some other commenters requested clarification that if an applicable manufacturer cannot identify an NPI for a physician then the NPI field can be left blank. Beyond determining a physician's NPI, a few commenters recommended that CMS clarify that physicians are not required to provide their NPI when requested and that applicable manufacturers should state that it will not be made public. Finally, some commenters recommended that CMS should require physicians to obtain NPIs to ensure that all physicians have one.

Response: We appreciate the comments, but want to reiterate that reporting a physician covered recipient's NPI is a statutory requirement, so the agency does not have flexibility to waive the requirement. Similarly, we do not believe that section 1128G of the Act provides the agency with authority to require all physicians to obtain an NPI. We agree that it may be difficult for an applicable manufacturer to definitively know whether a physician does not have an NPI; however we believe it is reasonable for the applicable manufacturer to bear responsibility for determining a physician covered recipient's NPI (or lack thereof). Applicable manufacturers should be able to demonstrate that they made a good faith effort to obtain an NPI for the physician. We believe that a good faith effort includes, but is not limited to, specifically requesting an NPI from the physician, checking the NPPES database, and calling the NPPES help desk. This statute does not impose requirements on covered recipients, so we do not believe we can require physicians to disclose their NPI to applicable manufacturers when requested; however, we strongly encourage physicians to provide this information because it is essential for matching payments or other transfers of value to physicians accurately. We believe it is in the best interest of all parties (applicable manufacturers, physician covered recipients, consumers and others) that payments be attributed to the correct physician, and we hope that physicians will be willing to provide their NPI to applicable manufacturers to make this possible, especially since their NPI will not be made public on the public Web site. If, after a good faith effort, the applicable manufacturer cannot determine an NPI for a physician covered recipient, or a physician does not have an NPI, we agree with the commenters and have finalized that the NPI field may be left blank to indicate that the applicable manufacturer could not identify an NPI for the physician covered recipient. However, if we determine that a physician covered recipient does have an NPI, we may inform the applicable manufacturer and require the applicable manufacturer to re-submit the data including the NPI and re-attest to the updated data. Additionally, not reporting an NPI for physician covered

[2] NPI Registry can be found at: *https://nppes.cms.hhs.gov/NPPES/NPIRegistryHome.do.*

[3] Database can be downloaded at *http://nppes.viva-it.com/NPI_Files.html.*

recipients that do have an NPI will be considered inaccurate reporting, which may be subject to penalties. Finally, we want to reiterate that only one *individual* NPI (not a group NPI) may be reported for each physician, and that applicable manufacturers should use the NPI listed in NPPES, if a dispute arises. Also as required by statute, physician-covered recipient's NPIs will *not* be included on the public Web site.

Comment: Some commenters discussed the proposal to allow reporting of an alternative identifier for physicians without an NPI. Many of these commenters supported reporting a State professional license number as an alternative to an NPI. Conversely, a few advocated that CMS not require an additional alternative unique identifier, whether it is a State professional license number or another identifier. Some commenters that supported State professional license number recommended that CMS should allow State professional license number instead of NPI at the discretion of the applicable manufacturer, since they believe it is could be burdensome for the applicable manufacturer to find the NPI.

Response: We agree that obtaining a unique identifier is particularly important for physicians who do not have an NPI or for whom an NPI cannot be reasonably identified. Without this information, it will be difficult for us to ensure that payments are attributed to the appropriate physician and to aggregate payments accurately. We believe that the more unique identifiers supplied for a physician covered recipient, the more accurate the data will be, since they are essential for us to appropriately match data about the same physician within and across reports, and publish data appropriately on the public Web site. Therefore, pursuant to the discretion granted in section 1128G(a)(1)(A)(viii) of the Act, we will finalize that applicable manufacturers *must* report the State(s) and appropriate State professional license number(s) for at least one (but multiple will be accepted) State where the physician maintains a license for all physician covered recipients, regardless of whether the applicable manufacturer has identified an NPI for the physician covered recipient or not. While this is slightly broader than what was proposed in the proposed rule, we believe (based on the comments) that reporting applicable State professional license numbers for all physician covered recipients, rather than only the subset that do not have NPIs, will significantly improve data accuracy and will not represent a significant additional burden on applicable manufacturers. Many commenters indicated that applicable manufacturers maintain this information already. Moreover, we believe that any additional burden associated with collecting and reporting physicians' State professional license numbers will be outweighed by the increased accuracy of the data attributing payments or other transfers of value to physician covered recipients.

Comment: Many commenters discussed the proposal that applicable manufacturers use NPPES to identify physician covered recipients. Many commenters did not support requiring applicable manufacturers to use the information listed in NPPES, rather than what was in their internal files, particularly for specialty and business address. The commenters explained that the data in NPPES is not as accurate in some cases, as their internal databases and information. Similarly, some commenters did not believe it made sense to report information from NPPES back to CMS. Many commenters also discussed how applicable manufacturers should use NPPES. These commenters inquired whether there would be point in time (such as 90 days before the reporting year) when the NPIs in the database would be finalized and no longer changed, and whether manufacturers could rely on it. A few commenters recommended that applicable manufacturers should be notified of changes in NPPES. For example, a commenter advocated that CMS should keep past ''versions'' of NPPES in case of an audit. In addition, some commenters stated that NPPES is not user friendly and CMS should be responsible for improving it. Finally, a few commenters requested that CMS create a list of physician covered recipients rather than using NPPES.

Response: We appreciate the comments on NPPES and note that we did not intend to require applicable manufacturers to specifically or solely use NPPES in order to obtain the NPI of a covered recipient. Applicable manufacturers may obtain physician NPI information (or any other information) in any manner they see fit, as long as they report NPIs accurately as required. This may include matching NPIs obtained elsewhere with the NPIs provided in NPPES. The NPPES database is continually updated, so it is difficult to set a point in time to freeze the database for a reporting year or notify applicable manufacturers of all changes. Applicable manufacturers may rely on NPI information in NPPES as of 90 days before the beginning of the reporting year.

However, just because an NPI is not listed in NPPES does not mean that the applicable manufacturer does not need to make a good faith effort to obtain the NPI or that the payment should not be reported. While it is not possible to keep past ''versions'' of NPPES due to the continual updates, we would like to point out that each provider entry is date stamped to include the date the entry was created, as well as the date of each update, which will help establish the information available at a particular time. Beyond the specific concerns regarding using NPPES, we understand that NPPES is not perfect, but the agency is working to improve it. In addition, we do not believe it is appropriate for us to create a new system specifically for this program, as it would be duplicative and unnecessary.

Finally, while we are sensitive to the request for a physician covered recipient list, we do not believe it is a viable option. Any list of physicians would be created based on NPPES, since it is the most comprehensive database available. However, as stated in this section, NPPES is not complete since not all physicians meeting the definition of covered recipient have an NPI. We also do not want the reporting requirements to be based on a list, which will be difficult to maintain and invariably include mistakes and inaccuracies. Instead, the statute that requires reporting of payments to physicians who meet the statutory definition. We believe applicable manufacturers are in the best position to identify the individuals with whom they have financial relationships who meet this definition.

(2) Identification of Teaching Hospitals

Regarding the identification of teaching hospitals, we proposed to publish a list of hospital covered recipients (that is, those hospitals that received Medicare direct GME or IME payments during the last calendar year for which such information is available) on the CMS Web site once per year. We proposed to do so since it may not be immediately apparent to applicable manufacturers whether a particular hospital meets our definition of a teaching hospital, and there is no currently published database that includes this information. We proposed that the list of teaching hospital covered recipients should include the name and address of each teaching hospital.

Comment: Many commenters supported CMS's proposal to publish a list of teaching hospitals, but recommended that the agency provide additional details regarding the list. The

commenters suggested that CMS publish the list prior to the beginning of the reporting year and ensure that applicable manufacturers will be able to download the list. The majority of these commenters recommended that the list be published 90 days before the end of the year, but the comments varied. Additionally, some commenters requested that CMS clarify that applicable manufacturers could rely on the teaching hospital list for the entire year and that entities not included on the list would not be covered recipients for the whole data collection year. They also advocated that the list should remove hospitals classified in error. Finally, a few commenters also requested that the list contain additional information to help clarify corporate identities (such as inclusion of a tax identification number (TIN) or an OSCAR number), as well as an institutional contact or officer for all hospitals.

Response: We agree that the teaching hospital list will be useful for applicable manufacturers and appreciate the comments making suggestions for how to improve the list. We will publish the list once annually and make it available publicly and for download at least 90 days before the beginning of the reporting year, or for the first reporting year, at least 90 days prior to the start of data collection. Applicable manufacturers can rely on the list for the entirety of the data collection year. The list will include all hospitals that CMS had recorded as receiving a payment under one of the defined Medicare direct GME or IME programs. The list will include hospital TINs to provide more specific information on hospitals with complex corporate identities. Finally, we will not include an institutional contact, since we do not have this information readily available and do not believe it is integral to the success of the program.

e. Payments or Other Transfers of Value

Section 1128G(a)(1)(A) of the Act requires that applicable manufacturers report a ''payment or other transfer of value'' made to a covered recipient or ''to an entity or individual at the request of or designated on behalf of a covered recipient.'' Under Section 1128G(a)(1)(B), if an applicable manufacturer makes a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a covered recipient, the applicable manufacturer must disclose the payment or other transfer of value under the name of the covered recipient. Section 1128G(e)(10)(A) of the statute defines ''payment or other transfer of value'' broadly as ''a transfer of anything of value.''

We would like to clarify that we interpret payments or other transfers of value to an entity or individual at the request of or designated on behalf of a covered recipient to refer to a situation in which an entity or individual receives and keeps the payment that was made on behalf of (or at the request of) the covered recipient and the covered recipient does not receive the payment or other transfer of value. Rather, the covered recipient directs the payment or other transfer of value and does not receive the payment personally. Such payments or other transfers of value to third party recipients are somewhat different than indirect payments to a covered recipient made through a third party (discussed in section II.B.1.k. of this final rule). Indirect payments or other transfers of value are made to an entity or individual (that is, a third party) to be passed through to a covered recipient. In the case of indirect payments or other transfers of value, we believe that the applicable manufacturer will generally direct the payment path.

We proposed that payments or transfers of value made to an individual or entity at the request of or designated on behalf of a covered recipient included payments or other transfers of value provided to a physician (or physicians) through a physician group or practice. We proposed that payments or other transfers of value provided through a group or practice should be reported individually under the name(s) of the physician covered recipient(s).

When reporting payments or other transfers of value made at the request of, or designated on behalf of a covered recipient, we proposed that applicable manufacturers should report the payment or other transfers of value in the name of the covered recipient, but include the entity or individual that received the payment at the request of or designated on behalf of the covered recipient. We believed that reporting the entity or individual paid would maximize transparency about the details of the payment or other transfer of value, by allowing end users to discern whether a covered recipient actually received the payment, and if not, where the payment went. Additionally, we proposed that we did not believe it was feasible to provide a review period for these entities before the data is made public. Instead, we explained that review by the covered recipient was sufficient.

Comment: Many commenters requested additional information on how to determine the amount and value of a payment or other transfer of value since neither the statute nor the proposed rule provided much guidance. While some commenters recommended specific options, such as interpreting value as discernible economic value on the open market, the majority advocated that the applicable manufacturers be allowed flexibility to determine whether a payment or other transfer of value has a cognizable economic value, and if so, to allow flexibility to determine such value. Several commenters also recommended that if a payment or other transfer of value does not have a measurable economic value to a covered recipient, then it does not need to be reported. In addition, a few commenters requested clarification on how to handle tax and other additional payments, such as shipping. Finally, a few commenters recommended that CMS clarify that goods purchased for market value should not be reportable.

Response: We appreciate the comments and agree that more information will be useful for applicable manufacturers. In general, for purposes of this rule only, we interpret value similarly to many comments as the discernible economic value on the open market in the United States. However, we agree and support that applicable manufacturers should be allowed flexibility to determine value, so we do not plan to create numerous rules for calculating value. We have outlined a few guidelines to help manufacturers. First, payments or other transfers of value that do not have a ''discernible'' economic value for the covered recipient specifically, but nevertheless have a discernible economic value generally must be reported. For example, an applicable manufacturer may provide a physician with a textbook that the physician already owns. Since it is a duplicate, it may not have a value to the physician; however, the textbook does have an economic value, so it must be reported. Second, even if a covered recipient does not formally request the payment or other transfer of value, it still must be reported. Similarly, when calculating value we believe that all aspects of a payment or transfer of value, such as tax or shipping, should be included in the reported value. Finally, all applicable manufacturers must make a reasonable, good faith effort to determine the value of a payment or other transfer of value. The methodology used and assumptions made by the applicable manufacturer may be included in the applicable manufacturer's voluntary assumptions document (discussed in section II.B.1.h.

of this final rule). Finally, we added the statutory definition of ''payment or other transfer of value'' to the regulatory text to ensure consistency with the statute.

Comment: A few commenters stated that applicable manufacturers should not report payments or other transfers of value provided to a group practice as if the payment or other transfer of value had been provided to all members of the group.

Response: We agree that payments or other transfers of value being provided to a specific physician through a group practice should not necessarily be attributed to all physicians in that group. However, we also do not want payments or other transfers of value to go unreported because they were provided to a group or practice rather than to a specific physician. This was the intent of our proposal for reporting payments to group practices. We have finalized that payments provided to a group or practice (or multiple covered recipients generally) should be attributed to the individual physician covered recipients who requested the payment, on whose behalf the payment was made, or who are intended to benefit from the payment or other transfer of value. This means that the payment or other transfer of value does not necessarily need to be reported in the name of all members of a practice. For example, if an applicable manufacturer donates a set of dermatology textbooks to a group practice, we believe that applicable manufacturers should attribute the transfer of value to only the dermatologists at the practice by dividing the cost equally across all dermatologists. We intend for applicable manufacturers to divide payments or other transfers of value in a manner that most fairly represents the situation. For example, many payments or other transfers of value may need to be divided evenly, whereas others may need to be divided in a different manner to represent who requested the payment, on whose behalf the payment was made, or who was intended to benefit from the payment or other transfer of value. We agree with the commenters that this approach attributes payments more fairly, since some physicians in a group practice may not make use of a payment or other transfer of value and may have concerns about such payments or other transfers of value being attributed to them.

Comment: A few commenters requested clarification of the reporting requirements for payments or other transfers of value provided through a covered recipient to another covered recipient. We did not address this specific situation in the proposed rule. These commenters generally refer to a situation when a payment is provided to a physician covered recipient, but made through a teaching hospital covered recipient.

Response: We appreciate the comments and agree that this is an area of potential confusion, so we believe that clarification is necessary. While the comments are generally limited to payments or other transfers of value to a physician through a teaching hospital, we provide clarification more generally. However, we recognize that the majority of payments to one covered recipient through another will likely involve a physician and teaching hospital.

Payments provided to one covered recipient, but directed by the applicable manufacturer to another specific covered recipient should be reported in name of the covered recipient that ultimately received the payment because the intermediate covered recipient was merely passing through the payment. For example, if an applicable manufacturer provides a payment to a teaching hospital intended for a physician employee of the teaching hospital, then the payment should be reported in the name of the physician covered recipient, since that is who ultimately received the payment. In addition, a payment provided directly to a physician covered recipient should be reported in the name of the physician, regardless of whether the physician is an employee of a teaching hospital, since the payment was provided to the physician and not the teaching hospital. In order to prevent double counting, payments provided in these circumstances should not also be reported in the name of the intermediate covered recipient. If the payment or other transfer of value was not passed through in its entirety, then the applicable manufacturer should report separately the portion of the payment or other transfer of value retained by the teaching hospital covered recipient and the portion passed through to the physician covered recipient. If the payment or other transfer of value was not passed through at all, the applicable manufacturer should report it in its entirety in the name of the teaching hospital. We note that the rules regarding research-related payments made to teaching hospital covered recipients differ somewhat and are discussed further in the section on research herein.

Comment: A few commenters recommended that CMS set a limit for the total amount a physician can receive annually.

Response: This statute does not afford us the authority to limit the payments or other transfers of value made to covered recipients. The statute requires applicable manufacturers to report the relationships, but does not limit or ban them in any way. This is a transparency initiative, and inclusion on the public Web site does not indicate that the relationships are necessarily improper or illegal.

Comment: There were a number of comments, some which supported reporting the name of the entity or individual that received the payment and others opposing this approach. However the most common suggestion was to only report the name of entities that receive the payment, rather than individuals, due to privacy concerns. Additionally, a few commenters stated that the applicable manufacturer may not know the amount if it was at the request or designated on behalf of a covered recipient.

Response: We appreciate the comments and continue to believe that reporting the name of the entity which received the payment at the request of or designated on behalf of a covered recipient is beneficial. However, we agree that reporting the name of an individual that received the payment could be problematic. We will finalize that applicable manufacturers must report, in the name of the covered recipient, all payments or other transfers of value made at the request of or designated on behalf of a covered recipient, as well as the name of the entity that received the payment or other transfer of value. In the event that a payment was provided to an individual, at the request of or designated on behalf of a covered recipient, the individual's name does not need to be reported. Instead, the applicable manufacturer should report simply ''individual'' in the field for entity paid.

Finally, we do not agree with the comment that the applicable manufacturer may not know the amount of the payment. We believe that because the applicable manufacturer is making the payment, it should know the amount being provided. We believe regardless of what entity received the payment or other transfer of value, the details are available to the applicable manufacturer.

Comment: Many commenters recommended that CMS should provide entities receiving payments or other transfers of value at the request of or designated on behalf of a covered recipient (as a third-party recipient) should have the opportunity to review and correct the information. However,

other commenters supported the CMS proposal.

Response: While we appreciate the interest in allowing these entities the opportunity for review, dispute and proposing corrections, we do not believe there is a viable method for administering it. The agency will not have any information on the entities beyond their name, so we will not be able to match an entity across applicable manufacturers. More importantly, since the entities will not be readily identifiable groups or individuals (such as physicians), the agency will have no means to validate the identity of an individual signing on to the Web site and stating that he or she is from a specific entity. Additionally, we believe a covered recipient will be able to review these payments or other transfers of value sufficiently since they should be aware of the payment or other transfer of value made at their request or designated on their behalf. As explained in this section, we have decided to only require reporting and publication of the name of entities (and not individuals) that received payments or other transfers of value at the request of or designated on behalf of covered recipients. We believe this should alleviate some of the concerns regarding review and correction because personal payments to an individual will not be made public on the Web site. Given these considerations, we will finalize that review and correction for entities which receive a payment at the request of or designated on behalf of a covered recipient will be done by the covered recipient, rather than the entity.

Comment: Numerous commenters noted various situations when a payment or other transfer of value may be at the request of or designated on behalf of a covered recipient. In some cases, a covered recipient may direct the payment elsewhere; conversely, in others, the covered recipient may simply waive the payment and the applicable manufacturer provides it to a third-party recipient of their choosing. In addition, there are also models when a covered recipient does not have any claim to the payment and it is automatically provided elsewhere (such as a charity) on his/her behalf. The commenters recommended various methods to report these situations, including categorizing some as non-reportable.

Response: We appreciate these comments and recognize that there are various circumstances where a payment will be made at the request of or on behalf of a covered recipient, which will all be slightly different. In general, we do not believe it will be possible to create rules for each situation. Instead, we are providing the following general guidelines and information on how we intend to interpret the phrases ''at the request of'' and ''designated on behalf of.''

If a covered recipient directs that an applicable manufacturer provide a payment or other transfer of value to a specific entity or individual, rather than receiving it personally, then the payment is being made ''at the request'' of such covered recipient and must be reported as described in this section (under the name of the covered recipient, but also including the name of the entity paid or ''individual,'' in the case of an individual). For example, in the event that a covered recipient directs an applicable manufacturer to donate a payment or other transfer of value—to which he would have otherwise been entitled—to a particular charity, the applicable manufacturer must report the payment in the name of the covered recipient and provide the name of the charity that received the payment at the covered recipient's request. However, if a covered recipient decides to neither accept the payment or other transfer of value nor request that it be directed to another individual or entity, then the payment or other transfer of value that was offered by the applicable manufacturer does not need to be reported. In this situation, there is nothing to report because no reportable payment or other transfer of value was made to a covered recipient or to an individual or entity at the request of or designated on behalf of a covered recipient.

In addition, we interpret ''designated on behalf of a covered recipient'' as when a covered recipient does not receive a payment or other transfer of value, but the applicable manufacturer provides the payment or other transfer of value to another entity or individual in the name of the covered recipient. For example, a covered recipient may waive his payment, and the applicable manufacturer nevertheless donates the payment to a charity ''on behalf of'' the covered recipient. We recognize that this could result in a covered recipient who waived a payment nevertheless having a payment reported in his or her name; therefore, we encourage covered recipients to make very clear to applicable manufacturers whether they would like their waived fee to be paid to another individual or entity—

After consideration of the public comments received, we are finalizing that reporting of payments or other transfers of value at the request of or designated on behalf of a covered recipient should be reported, but should include the name of the entity paid or that another individual received the payment. The covered recipient will have the opportunity to review and correct the payment on behalf of the entity or individual that received the payment.

f. Payment and Other Transfer of Value Report Content

The specific categories of information required to be reported for each payment or other transfer of value provided to a covered recipient are set forth in section 1128G(a)(1)(A) of the Act. In the proposed rule, we provided explanations and details on how we proposed that applicable manufacturers report some of this information to CMS. This section outlines the comments we received on the data elements.

(1) Name

We proposed that applicable manufacturers should report the first name, last name, and middle initial for physician covered recipients.

Comment: A few commenters stated that not all physicians have middle names and not all existing systems include middle name or initial, so they recommended middle initial not be reported.

Response: We appreciate the comments, but believe that given the number of physicians with the same first and last name, reporting a middle initial will be important when identifying and distinguishing physician covered recipients and aggregating payments across applicable manufacturers. While we recognize that not all physicians have middle names, we believe that this information should be reported whenever possible. As required in § 403.904(c)(1), applicable manufacturers must report the middle initial of a physician covered recipient as listed in NPPES, but will not be penalized for leaving the field blank if it is not available in NPPES or if the physician does not have a middle name. Additionally, as stated previously, we hope that applicable manufacturers provide as much identifying detail as possible on physician covered recipients to ensure we can attribute payments appropriately. In order to ensure that physician covered recipients are appropriately matched across applicable manufacturers and to their own data during the review and correction period, we will require applicable manufacturers to report a physician covered recipient's name as listed in NPPES.

(2) Business Address

We proposed that applicable manufacturers should report the full street address. For teaching hospital covered recipients, we proposed using only the address included in the CMS-published list of teaching hospitals. For physician covered recipients, we proposed that applicable manufacturers report the physician's primary practice location address, since this is more easily recognizable to end users of the data.

Comment: A few commenters recommended that CMS allow applicable manufacturers to use the address kept on file for a physician covered recipient, rather than the address in NPPES, since the address on file may be more accurate than the NPPES address. Regarding NPPES, a few commenters also suggested that CMS should require physicians to keep their address updated. Some commenters recommended reporting the address used for correspondence, rather than business location. Finally, a few commenters discussed that providing the full street address for the business address field for each payment or other transfer of value will increase the data elements significantly.

Response: We appreciate the comments. We agree that (unlike with a physician covered recipient's name) applicable manufacturers do *not* need to use NPPES when reporting addresses. In the proposed rule, we simply wanted to be clear that it was available and explain what field to use, if an applicable manufacturer chose to use NPPES. Regarding the requirement to keep addresses updated, we encourage physicians to keep their NPPES profiles updated, but we do not believe that we have the authority to force all physicians to do so.

We also have finalized our proposal to require the primary practice location address to be reported as the business address. We realize that a physician can be associated with multiple addresses, but we believe that primary practice location is the most recognizable to consumers. However, we understand that it may be difficult for an applicable manufacturer to know which address represents the primary practice location, so we plan to not penalize applicable manufacturers for providing the incorrect address, as long as applicable manufacturer reports a legitimate business address for the covered recipient.

Finally, we appreciate the comment that the reporting of a full street address (as opposed to a portion of the address, such as City and State) will require a significant amount of data to be submitted. We agree that we want to minimize the data submitted; however, we believe that full street address is important since in large urban areas there may be multiple physicians with the same name in the same city, so we will continue to require reporting of full street business address.

(3) Specialty and NPI

In the proposed rule, we stated that, as required by the statute, applicable manufacturers are required to report the specialty and NPI for physician covered recipients. We suggested that applicable manufacturers use the ''provider taxonomy'' field when reporting physician specialty. We proposed that applicable manufacturers only report a single specialty and use only the specialties available for the ''provider taxonomy'' field in NPPES. More details on these terms are available online.[4] For NPI, we proposed that applicable manufacturers report the physician's individual NPI, rather than any group NPI, with which the physician may be associated.

Comment: Many commenters addressed the requirements for reporting physician specialty and NPI. Some commenters recommended that applicable manufacturers be able to use their own internal files for reporting specialty, rather than NPPES. They were concerned that specialty in NPPES may not be accurate and could lead to concerns about off-label marketing. Regarding the NPPES list, a few commenters recommended that CMS include the nine recognized American Dental Association (ADA) specialties. Some commenters also requested clarification on whether applicable manufacturers should report both the specialty name and the associated NPPES code. In addition, a few commenters recommended that CMS allow methods for an applicable manufacturer to provide more context regarding physician specialty, such as reporting multiple specialties with one listed as primary or allowing a statement justifying specialty choice.

Response: We appreciate the comments and agree that applicable manufacturers may use their internal information when reporting specialty. However, the NPPES ''provider taxonomy'' list (as referenced previously) should be used as the list of accepted specialties since consistency in the names of reported specialties is important for facilitating aggregation of the data. We note that the NPPES list does include the nine recognized ADA specialties. When reporting specialty, applicable manufacturers should list both the specialty name and code to ensure consistency.

Additionally, we do not believe applicable manufacturers need to provide more information when reporting physician covered recipient specialty. We believe that a single specialty should be sufficient and that allowing applicable manufacturers to provide a justification of physician specialty would be too much information to be beneficial.

(4) Date of Payment

In the proposed rule, we required applicable manufacturers to provide the date on which a payment or transfer of value was provided to the covered recipient. We recognized that some payments or other transfers of value might be provided over multiple dates, such as a consulting agreement with monthly payments. We proposed that applicable manufacturers use their discretion as to whether to report the total payment on the date of the first payment as a single line item, or to report each individual payment as a separate line item.

Comment: Many commenters supported the proposed requirements for reporting the date(s) of payment. These comments appreciated the flexibility since applicable manufacturers may use different tracking systems. However, some commenters requested additional flexibility on how to report the payment date. For example, some commenters suggested that applicable manufacturers should have flexibility, depending on their individual systems, to report the date a flight actually occurred or the date the trip was booked, as long as this information is reported consistently within a category. Additionally, the commenters recommended that CMS clarify how to report payments which may happen across a reporting year.

Response: We appreciate the comments and have finalized the proposal that applicable manufacturers have the flexibility to report payments made over multiple dates either separately or as a single line item for the first payment date. In addition, we will allow flexibility for what specific date to report for a nature of payment category. We believe that the methodology employed should be consistent within a single nature of payment category. For example, for all flights, applicable manufacturers should report dates in a consistent manner (such as the flight

[4] Health care provider taxonomy codes are available through a link on the NPPES Web site: *https://nppes.cms.hhs.gov/NPPES/StaticForward.do?forward=static.instructions.*

date or ticket purchase date). In addition, the aggregated payments should not cross years, so for payments which span multiple years, the amount paid in a given year must be reported for that reporting year. Similarly, the date of payment methodology should not be used to move payments from one reporting year to another. Applicable manufacturers are encouraged to include information on the methods they used for reporting date of payment or other transfer of value in their assumptions document. When reporting the date of payment for bundled small payments (as described in § 403.904(i)(2)(iv)), applicable manufacturers should report the date of payment as the date of the first small payment or other transfer of value made to the covered recipient.

(5) Context

Comment: Some commenters recommended that CMS allow applicable manufacturers to voluntarily report contextual information about each payment or other transfer of value and make the information publicly available. CMS did not propose including this in the proposed rule.

Response: We agree that information on the context of a payment or other transfer of value could be useful. We believe it could help the public better understand the relationships between the industry and covered recipients. In addition to consumers, we believe contextual information will be useful for covered recipients when reviewing the payments or other transfers of value. Hopefully, the context will provide information to help the covered recipient assess the accuracy of the payment. However, we do not want this information to overwhelm users or significantly increase the data reported, so will limit the amount of data that can be reported in that field. Section 403.904(c)(12) allows applicable manufacturers to provide brief contextual information for each payment or other transfer of value, but does not require them to do so.

(6) Related Covered Drug, Device, Biological or Medical Supply

Section 1128G(a)(1)(A)(vii) of the Act requires applicable manufacturers to report the name of the covered drug, device, biological or medical supply associated with that payment, if the payment is related to ''marketing, education, or research'' of a particular covered drug, device, biological, or medical supply. We proposed that in cases when a payment or other transfer of value is reasonably associated with a specific drug, device, biological or medical supply, the name of the specific product must be reported. We realize that not every financial relationship between an applicable manufacturer and a covered recipient is explicitly linked to a particular covered drug, device, biological or medical supply, but many are, and we proposed that those must be reported.

When reporting a related product, we proposed that applicable manufacturers could report only one covered drug, device, biological or medical supply as related to a payment or other transfer of value, even though there arguably may be multiple covered products related to the payment. However, we considered, as an alternative, allowing applicable manufacturers to report multiple covered drugs, devices, biologicals or medical supplies as related to a single payment or other transfer of value. We believed that reporting of multiple covered drugs, devices, biologicals, and medical supplies may be easier for applicable manufacturers since many financial relationships are not specific to one product only, but could make aggregating payments by product difficult.

With regard to reporting a product name, we proposed that the applicable manufacturer should report the name under which the product is marketed, since this name is probably most recognizable to the consumer. In the event that a covered drug, device, biological or medical supply does not yet have a market name, we proposed the applicable manufacturer should report the scientific name.

Comment: Many commenters questioned how and when to report an associated product. A number of these commenters discussed whether a product name should be reported for payments associated with non-covered products (such as pre-commercial or OTC drugs) and recommended only requiring reporting of a product when the payment is related to ''marketing, education, or research.'' Many commenters also recommended that CMS allow the reporting of ''n/a'' or ''none'' in instances when a product is not associated or when associated with a non-covered product. Similarly, a few commenters recommended that applicable manufacturers should not have to report an associated product for research on a new indication of a covered product.

A few commenters provided more specific requirements, such as only reporting a covered product for a payment or other transfer of value, when there is a written agreement or an understanding with the covered recipient that the product will be named. Similarly, some commenters suggested that CMS should allow flexibility to report business purpose, in addition to product family or a single product.

Response: We appreciate the comments and agree that it is important to provide additional information on when and how a related product should be reported. Section 1128G(a)(1)(A)(vii) of the Act requires that ''if a payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply,'' applicable manufacturers must report the name of the covered product. We believe that many financial relationships between applicable manufacturers and covered recipients are related to marketing, education or research associated with a particular product, often a covered product. Therefore, we will finalize that applicable manufacturers must report a related product name for all payments or transfers of value, unless the payment or other transfer of value is not related to a covered product. However, we do not believe applicable manufacturers should be required to report the name of associated non-covered products, since this may be misleading to consumers and would provide information that is beyond the goal of the statute. However, we do believe it is useful to know the extent of payments or other transfers of value that are not associated with *any* product or not associated with a *covered* product. This distinction will not be possible if applicable manufacturers leave the associated products fields blank in cases when it is not applicable. Given this interest, the final rule directs applicable manufacturers to fill in associated product fields as appropriate. Instead, if the payment or other transfer of value is not related to at least one covered product, then applicable manufacturers should report ''none.'' Conversely, if the payment or other transfer of value is related to a specific product, which is not a covered product, then applicable manufacturers are to report ''non-covered product.'' Finally, if the payment or other transfer of value is related to at least one covered product, as well as at least one non-covered product, then applicable manufacturers must report the covered products by name (as required), and may include non-covered products in one of the fields for reporting associated product.

Comment: Many comments addressed the number of associated products that may be reported for each payment or other transfer of value. Several commenters supported allowing

reporting of only a single product, whereas several others supported allowing applicable manufacturers to report multiple products as being associated with the a payment or other transfer of value. The commenters who advocated reporting multiple products explained that often a financial relationship is associated with multiple products, and it would be misleading to attribute it to a single product. Conversely, some commenters were sympathetic to the need to aggregate the payments or other transfers of value by product. As a compromise, some of these commenters suggested reporting a single product would be sufficient, as long as we allowed applicable manufacturers to report ''multiple,'' as well. Other commenters recommended that CMS allow reporting of up to five products. However, these comments cautioned that aggregation by product should not give the impression that there were multiple interactions. A commenter recommended requiring applicable manufacturers to report a percentage of the interaction to be attributed to each product listed. The comments also addressed what product name should be used. Many commenters advocated that applicable manufacturers should be allowed to report the product category or therapeutic area rather than the product-specific name. Many commenters recommending this method referenced implantable devices, since consumers may not know the specific name of the device that had been implanted during a medical procedure. Many devices are given a complex name and number combination, which consumers may not know. For example, a patient may be aware that she received a hip implant manufactured by company A, but may not know the specific model number of the implant. Similarly, some commenters recommended slight changes to the name required to be reported, such as using the clinicaltrials.gov name for drugs without a name or allowing reporting of the generic name. Finally, a few commenters suggested that we require reporting of National Drug Code (NDC), as well as brand and generic name.

Response: We appreciate the comments and agree that reporting multiple products will likely improve the accuracy of the database in a way that is more beneficial than the difficulty in aggregating by product. Therefore, we will finalize that applicable manufacturers may report up to five related covered products for each interaction. If the interaction was related to more than five products, an applicable manufacturer should report the five products which were most closely related to the payment or other transfer of value. Additionally, when aggregating payments or other transfers of value by product, we will not represent a single interaction related to multiple products as multiple interactions. However, we do not agree that the applicable manufacturer should report the percentage of the interaction dedicated to each product. We believe this will be burdensome to the applicable manufacturers and would not be beneficial to consumers, since it will greatly increase the volume of the data.

We also agree that we should allow greater flexibility in reporting the product name, particularly for devices where the product name is less recognizable to consumers. For drugs and biologicals, we are finalizing that applicable manufacturers must report the market name of the product and must include the NDC (if any). If a market name is not yet available, applicable manufacturers should use the name registered on clinicaltrials.gov. We believe that reporting the NDC will greatly help CMS aggregating the data by product. However, if there is no NDC available for a product, it does not have to be reported. For devices and medical supplies, § 403.904(c)(8)(ii) allows reporting of either the name under which the device or medical supply is marketed, or the therapeutic area or product category. We believe that reporting devices and medical supplies in this manner is appropriate, since device names are less known to consumers and a single product may actually be comprised of multiple devices. Conversely, we believe that the names of drugs and biologicals are more readily available to consumers, since they are often listed on a prescription.

(7) Form of Payment and Nature of Payment

The statute requires reporting on both the form of payment and the nature of payment for each payment or transfer of value made by an applicable manufacturer to a covered recipient. The statute provides a list of categories for both the form of payment and nature of payment and gives the Secretary discretion to add additional categories.

Section 1128G(a)(1)(A)(v) of the Act includes the following form of payment categories:

- Cash or a cash equivalent.
- In-kind items or services.
- Stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment.
- Any other form of payment or other transfer of value.

Section 1128G(a)(1)(A)(vi) of the Act includes the following nature of payment categories:

- Consulting fees.
- Compensation for services other than consulting.
- Honoraria.
- Gift.
- Entertainment.
- Food.
- Travel (including the specified destinations).
- Education.
- Research.
- Charitable contribution.
- Royalty or license.
- Current or prospective ownership o investment interest.
- Direct compensation for serving as faculty or as a speaker for a medical education program.
- Grant.
- Any other nature of the payment or other transfer of value.

In this section, we discuss the general policies for reporting the form of payment and the nature of payment, rather than the specific categories, which will be discussed in sections II.B.1.g and h. of this final rule.

In the proposed rule, we proposed that the categories within both the form of payment and the nature of payment should be defined as distinct from one another. Additionally, if a payment or other transfer of value for an activity is associated with multiple categories, such as travel to a meeting under a consulting contract, we proposed that the travel expenses should remain distinct from the consulting fee expenses and both categories would need to be reported to accurately describe the relationship. In these cases, we proposed that for each payment or other transfer of value reported, applicable manufacturers may only report a single nature of payment and a single form of payment. For example, if a physician received meals and travel in association with a consulting fee, we proposed that each segregable payment be reported separately in the appropriate category. The applicable manufacturer would have to report three separate line items, one for consulting fees, one for meals and one for travel. The amount of the payment would be based on the amount of the consulting fee, and the payments for the meals and travel. For lump sum payments or other transfers of value, we proposed that the applicable manufacturer break out the distinct parts of the payment that fall into multiple categories for both form of payment and nature of payment. We also solicited comment on an alternative approach of allowing a payment or other transfer of value for an activity that is

associated with multiple segregable categories to be reported as a single lump sum, rather than separately by each segregable category.

Finally, in the proposed rule we also discussed the interpretations of various forms of payment and natures of payment categories. We did not define the categories individually and instead proposed that they would have their dictionary definitions.

Comment: Many commenters addressed our proposed method for reporting form of payment and nature of payment. A number of these commenters supported our proposed method of reporting a single form of payment and a single nature of payment for each reported payment, whereas others supported the alternative of reporting multiple forms of payment and natures of payment for a single payment. The commenters supporting multiple forms of payment and natures of payment recommended that the applicable manufacturer should be allowed flexibility to report, but should explain their decisions and methodology for reporting form and nature of payment in the assumptions document. Additionally, a few commenters suggested that the applicable manufacturer should be allowed to report lump payments, but should be required to produce segregated payments in an audit. Finally, a few commenters recommended that CMS allow applicable manufacturers to report additional details beyond form of payment and nature of payment to allow end users to understand that not all reported relationships are payments.

Response: We appreciate the comments and believe they provided important background on the processes of reporting. However, we have finalized these provisions as proposed. We believe that flexibility in the reporting requirements is important to aid applicable manufacturers with different systems. However, we believe that there should also be consistency in the way payments or other transfers of value are reported across applicable manufacturers, particularly when describing and classifying payments or other transfers of value. We believe that a single form of payment and a single nature of payment for each line item characterizes a payment or other transfer of value much differently than reporting multiple forms of payment and natures of payment for a lump sum payment. We are concerned that allowing this flexibility will be confusing to covered recipients and end users, since they will not be able to readily tell a specific applicable manufacturer's method for reporting the payment or other transfer of value, since the assumptions document will not be made public. We also believe that a flexible method would create additional disputes because a covered recipient would not know what was included in a single line item, since some line items would be separated, whereas others would be aggregated. Additionally, a State with a similar reporting requirement for manufacturers that allows the reporting of secondary natures of payment stated in its public comment that reporting entities seldom use the secondary field, indicating that a single field should be sufficient.

With regard to choosing the appropriate nature of payment, we agree that if a payment could fit within multiple possible categories, applicable manufacturers should have flexibility to select the category that best described the payment, in accordance with their own documented methodology. However, this should not be used to bundle payments of separate categories into a single payment. For example, a meal should be reported as a meal, even if associated with travel or a consulting contract. Additionally, serving as a faculty for a medical education program should be reported separately from a consulting contract, even if the medical education program speech was similar in content to the consulting services provided by the covered recipient.

Comment: A number of commenters generally questioned the form of payment and nature of payment categories. Many commenters requested that CMS develop precise definitions, and a few commenters provided recommended definitions. However, in the event that the agency does retain the dictionary definitions, some commenters suggested that CMS should ensure that the dictionary definitions are sufficient to provide clarity. Additionally, a few commenters recommended that CMS publish and allow for Q&As to further clarify the categories. A few commenters provided additional categories for CMS to add, whereas others recommended methods for categorizing payments or other transfers of value to explain the details of the payment. For example, a commenter recommended that we create separate reporting categories for payments or other transfers of value made directly and indirectly. Finally, a few commenters recommended that we should consider form of payment as ''payment type'' or the modality used to transfer value, whereas we should consider nature of payment as ''payment nature'' or the reason the payment was made.

Response: We appreciate the comments and have carefully considered the best way to provide additional context to the categories. Given the very specific statutory requirements, we are unable to fully reconfigure the categories; while the Secretary is granted discretion to add forms of payment and natures of payment, she is not given discretion to remove or collapse them. However, we appreciate the clarification on form of payment being considered the modality used to transfer value and nature of payment being the reason the payment was made. We believe these classifications should help applicable manufacturers when assigning categories, and will help us provide more accurate guidance on the categories.

In order to provide additional information we have provided general discussions and additional contextual information, particularly for the nature of payment categories, since we believe most comments were concerned with the nature of payment categories. We provide additional details in the following two sections of this final rule dedicated to form of payment and nature of payment.

g. Form of Payment

Section 1128G(a)(1)(A)(v) of the Act lists forms of payment that applicable manufacturers must use to describe payments or other transfers of value. Applicable manufacturers must assign each individual payment or other transfer of value, or separate parts of a payment, to one and only one of these categories. In the proposed rule, we did not add any forms of payment beyond those outlined in the statute because we believed what is provided in the statute was sufficient to describe payments and other transfers of value. Additionally, as explained, we proposed that each form of payment be defined by the term's dictionary definition, since we believed that these terms are understandable as written.

Comment: We received a few comments supporting the categories, as well as a few recommending small changes to the categories. A few commenters advocated adding a category for ''grant'' to make clear that it was not personal income. Another few commenters recommended separating stock, stock option, or any other investment interest from dividend, profit or other return on investment, since they are materially different. These commenters explained that stocks, stock options, and investment interests are different from dividends, profits, and return on investments

because the former are actively granted to a covered recipient while the latter are earned on existing investments. Finally, regarding the definitions, a few commenters suggested that CMS use standard legal definitions.

Response: We appreciate the comments and agree that the forms of payment categories are sufficient. However, we do agree that the ''stock, stock option, or any other ownership investment interest, dividend, profit or other return on investment'' category should be divided into two categories. We agree that the categories are different and separating them would create additional specificity in the categories, without changing them significantly. Conversely, we do not agree that grant should be a form of payment. Instead, we believe ''grant'' should remain as a nature of payment (as included in the statute), since it best describes a reason a covered recipient might receive a payment. After consideration of the public comments received, we are finalizing the proposal to break the category of ''stock, stock option, or any other ownership investment interest, dividend, profit or other return on investment'' category into two categories, but otherwise will not be adding any additional categories to form of payment. We agree that stock, stock options, and other ownership investment interests are different than dividends, profits and other returns of investment, so separating these categories may provide additional clarity to consumers. We do not believe that this changes the way forms of payments will be reported, since the categories existed previously, we are simply providing more clarity and specificity to the categories. We believe the dictionary definitions are sufficient, particularly since these terms are generally understandable to consumers.

h. Nature of Payment

Section 1128G(a)(1)(A)(vi) of the Act lists the categories for the nature of payment or other transfer of value that applicable manufacturers must use to describe each payment. In the proposed rule, we encouraged applicable manufacturers to consider the purpose and the manner of the payment or other transfer of value; if a payment could conceivably fall into more than one category, we proposed that applicable manufacturers should make reasonable determinations about the nature of payment reported for the payment or transfer of value. Additionally, as explained, we believed that the nature of payment categories have meanings to the general public that are familiar to the industry and proposed defining each nature of payment category by its dictionary definition.

Comment: Many commenters discussed the nature of payment categories, including our proposed method for defining the categories. A few commenters recommended that CMS provide more guidance on how these categories should be applied. For example, one commenter recommended that CMS rank the categories and if multiple categories could apply to a single payment or other transfer of value, the applicable manufacturer should report it in the ''higher'' ranked category. Another commenter requested that CMS break the categories into two groups: those made in exchange for value (such as services or intellectual property rights) and those made without any expectation of benefit. Beyond categorizing payments or other transfers of value, many commenters requested additional guidance on the definitions for the nature of payment categories. We also received a few recommendations for additional nature of payment categories. For example, a few commenters recommended including a category for agreements to appear as an ''author'' of an industry ghost-written publication. Another commenter recommended that we include a category for space or facility fee for events at a teaching hospital.

Response: We appreciate the comments. However, we believe that providing precise definitions for applicable manufacturers to use in categorizing nature of payments will be too restrictive. Applicable manufacturers are required to report all payments or other transfers of value, unless they specifically fall within an exception. The nature of payment categories are simply used to *describe* these payments or other transfers of value. We believe precise definitions could make these descriptors less useful and could make reporting more challenging for applicable manufacturers. For example, if a payment or other transfer of value that the applicable manufacturer generally would classify as a consulting fee does not meet our precise definition, the applicable manufacturer would be forced to report it in another category, which would likely be less accurate than the consulting fee category. The relationships between applicable manufacturers and covered recipients are extremely diverse; we are concerned that providing specific, narrow definitions would not encompass every situation, forcing applicable manufacturers to describe payments or other transfers of value by less specific categories that do not accurately describe the relationship. Additionally, since all payments or transfers of value must be reported, we do not believe we should rank the categories and indicate some as more desirable or beneficial than others. Instead, we believe that the nature of payment categories are descriptors and that applicable manufacturers should select the most appropriate description. However, we do understand the interest in consistency to enhance of the usefulness of the data, so we will provide some additional explanations for the categories.

Finally, we appreciate the recommended additional categories. We have tried to limit the number of additional categories as much as possible, so we have only added categories for those recommendations that we believe cannot be described by existing nature of payment categories. For example, we believe that agreement to appear as an author of a ghostwritten article is an important relationship that should be reported, but believe there are sufficient existing nature of payment categories, such as compensation for services other than consulting, which can be used to describe the relationship. Conversely, regarding space rentals, we do agree that this represents a specific relationship between a covered recipient (likely a teaching hospital) and an applicable manufacturer that cannot be accurately described by the existing nature of payment categories. We understand that space rental or facility fees are commonly part of hosting an event at a hospital and believe that including them in another category would inflate the amount in that category. Similarly, the statutory nature of payment categories are mostly directed towards physician covered recipients, so it is important to consider the common relationships between teaching hospital covered recipients and applicable manufacturers. Given these considerations, we will add space rental and facilities fees as a nature of payment category under our authority in section 1128G(a)(1)(A)(vi)(XV) of the Act, but will not add appearing as an author for a ghostwritten article.

We are providing some additional explanation of the nature of payment categories to provide additional context. These explanations are not exhaustive (unless specified as such), but rather are intended to provide additional guidance to applicable manufacturers when they are categorizing payments. Additionally, we will discuss research in a separate section in light of the additional complexities in reporting research-related payments or other transfers of

value, which warrants additional consideration.

(1) Charitable Contributions

In the proposed rule, we stated that charitable contributions to, at the request of, or on behalf of covered recipients by applicable manufacturers must be reported. For purposes of the reporting requirement, a charitable contribution is any payment or transfer of value made to an organization with tax-exempt status under the Internal Revenue Code of 1986, but only if it is not more specifically described by one of the other nature or payment categories. We did not receive any comments on the definition of charitable contribution and intend to finalize it as proposed.

Comment: Many commenters questioned how to report payments or other transfers of value for when a covered recipient (usually a physician) does not receive a payment personally and instead the payment is provided to a charity. In these situations, the covered recipient may or may not choose the charity and may be waiving his or her customary fee.

Response: We appreciate the comments and understand these payments or other transfers of value can be complicated. We discussed general guidelines for reporting payments through another covered recipient in the payments or other transfer of value section of the final rule, but will provide additional detail in this section for situations when a payment or other transfer of value is directed to charity. We believe that the ''charitable contribution'' nature of payment category should be used only in situations when an applicable manufacturer makes a payment or other transfer of value to a charity on behalf of a covered recipient and not in exchange for any service or benefit. For example, in circumstances where a physician provides consulting services to an applicable manufacturer, but requests that his payment for the services be made to a charity, this would not be a charitable contribution for purposes of this rule because the payment was not provided by the applicable manufacturer as a charitable contribution, but rather as a directed consulting fee. This payment would be reported as a consulting fee with the physician as the covered recipient, but the entity paid would be the charity.

Additionally, we note that in the cases of teaching hospital covered recipients that have tax-exempt status under the Internal Revenue Code of 1986, payments or other transfers of value made to these organizations (other than payments or other transfers of value made for expected services or benefits, such as consulting services or rental of space in a hospital for an event) would be considered and reported as charitable contributions for purposes of this rule.

(2) Food and Beverage

When reporting food and beverage, we proposed that in group settings, such as the office of a group practice, where it is more difficult to keep track of which covered recipients actually partook in the food and beverage provided by an applicable manufacturer, the applicable manufacturer should report the cost per covered recipient receiving the meal even if the covered recipient does not actually partake of the meal.

Comment: Numerous commenters questioned our proposed allocation method for food and beverage. The majority of commenters recommended that we revise our proposed allocation methodology, but we did receive some support for it. Many commenters recommended various options for dividing the cost of group meals; however, there were some common themes in the recommendations. The majority of these commenters recommended that applicable manufacturers should report the amount based on the cost per participant (including, for example, support staff members who are not covered recipients), rather than the cost per covered recipient. Many commenters also strongly recommended that we should not attribute meals to *all* covered recipients in a practice because it may be difficult for applicable manufacturers to identify all the physicians within a practice, and this methodology could implicate concerns of off-label marketing in large multispecialty practices. These commenters suggested that the cost of a meal should only be attributed to physicians who actually partook of the food. They suggested that it would not be unduly burdensome to keep track of which physicians actually participated in the meal. Some commenters also recommended that CMS allow applicable manufacturers flexibility in allocating the value of meals depending on their internal systems or that the value should be based on the amount actually received. Finally, a few commenters recommended that CMS provide covered recipients with the opportunity to ''opt-out'' of interactions with applicable manufacturers, including meals, and attest that they never partake in such meals.

Beyond the allocation method, we received significant support for our proposal that applicable manufacturers do not need to report any offerings of buffet meals, snacks or coffee at booths at conferences or other similar events where it would be difficult for applicable manufacturers to definitively establish the identities of the individuals who accept the offerings. However, a few commenters also recommended that meals that are dropped off at a physician's office should also be excluded, as well as meals when the attendees are outside the control of an applicable manufacturer.

Response: We appreciate the comments and understand that reporting payments or other transfers of value that fall under the ''food'' nature of payment category is quite complicated, both in terms of calculating the value of the payments and determining who should be reported as having received payments. We believe that while reporting the transactions accurately is important, tracking exactly what a person ate or drank may not be practical for purposes of the reporting requirements. We have considered how to improve accuracy in reporting, while ensuring that the reporting requirements for this nature of payment are not overly burdensome. For meals in a group setting (other than buffet meals provided at conferences or other similar large-scale settings), we will require applicable manufacturers to report the per person cost (not the per covered recipient cost) of the food or beverage for each covered recipient *who actually partakes in the meals* (that is, actually ate or drank a portion of the offerings). In other words, applicable manufacturers should divide the total value of the food provided by the number of people who actually partook in the food and beverage including both covered recipients and non-covered recipients (such as support staff). If the per person cost exceeds the minimum threshold amount, then the applicable manufacturer must report the food or beverage as a payment or other transfer of value for each covered recipient who actually participated in the group meal by eating or drinking a food or beverage item. For example, a sales representative brings a catered lunch costing $165 to a 10-physician group practice. Six of the ten physicians and five support staff participate in the meal. Because the meal cost $15 per participant ($165/11 participants = $15), the meal needs to be reported for the 6 physicians who participated in it. However, the meal does not need to be reported for the 4

other physicians in the group who did not participate in the meal (that is, did not eat or drink any of the offerings). Additionally, if the total cost of the meal was $100, making the cost per participant less than $10, then the meal would not have to be reported since it was below the minimum threshold. We decided to make this modification to the proposed rule because we agree with commenters that for the purposes of this rule this method will more accurately reflect the actual transaction, and will not unfairly attribute a payment to a physician who did not partake in it. Additionally, we believe this approach will reduce disputes between applicable manufacturers and physicians, since food-related payments or other transfers of value will not be attributed to physicians that did not actually receive them. Finally, this method does not require the reporting of meals eaten by support staff, for the purposes of this reporting requirement. However, we recognize that in other contexts, transfers of value to a physician's office support staff (which may include meals) may constitute transfers of value to the physician.

While we appreciate the importance of flexibility, we believe that we need to set out the attribution methodology in order to ensure as much consistency as possible. If we did not provide a methodology, it could result in very different amounts being reporting across applicable manufacturers and could lead to increased disputes since covered recipients would not know how a particular applicable manufacturer attributed the value of a meal. We believe that there must be some consistency across applicable manufacturers in this complicated area, so we have finalized the position that applicable manufacturers must report the cost per participant for covered recipients in attendance.

Regarding meals that are dropped off at a covered recipient's office (for example, by a sales representative) and other meals where the attendees are not controlled or selected by the applicable manufacturer, we believe that these situations nevertheless constitute payments or other transfers of value to a covered recipient, so they must be reported. Applicable manufacturers are responsible for keeping track of food and beverages provided to covered recipients and must use the same attribution method for all meals as described previously regardless of whether the manufacturer's representative remained in the office for the entire meal.

We also appreciate the comments regarding allowing covered recipients the opportunity to opt-out from receiving meals; however, we believe that this would be operationally difficult for CMS. We would need to track the covered recipients and would have to develop a method of arbitration if an applicable manufacturer reports a meal for a physician who has opted-out. We believe that covered recipients who do not want to receive meals simply should make clear to applicable manufacturers that they do not accept them. The finalized methodology will no longer attribute meals to physicians who do not attend the meal, so a physician who does not want to receive meals should not attend or accept them.

Finally, we appreciate the support regarding offerings of buffet meals, snacks, or coffee at conferences or other large-scale events where it would be difficult for applicable manufacturers to definitively establish the identities of the physicians who partake in the food or beverage. Accordingly, we have finalized that food and beverage provided at conferences in settings where it would be difficult to establish the identities of people partaking in the food do not need to be reported. This applies to situations when an applicable manufacturer provides a large buffet meal, snacks or coffee which are made available to all conference attendees and where it would be difficult to establish the identities of the physicians who partook in the meal or snack. We do not intend this to apply to meals provided to select individual attendees at a conference where the sponsoring applicable manufacturer can establish identity of the attendees.

(3) Direct Compensation for Serving as a Faculty or as a Speaker for a Medical Education Program

In the proposed rule, we interpreted this category broadly to encompass all instances in which applicable manufacturers pay physicians to serve as speakers, and not just those situations involving ''medical education programs.'' We acknowledged that this interpretation does not allow for differentiation between continuing education accredited speaking engagements, and all other speaking engagements.

Comment: Many comments addressed our proposed interpretation of this category, particularly regarding its relationship to accredited and/or certified continuing medical and dental education.

A few commenters supported our interpretation to include all speaking engagements in one category; however, numerous others were concerned about payments for accredited and/or certified continuing education-related speaking engagements and recommended that they be treated differently than unaccredited and/or certified continuing education speaking engagements. Many of these commenters provided significant background information on accredited and certified continuing education. Accredited Continuing Medical Education (CME) refers to CME activities that have been deemed to meet the requirements and standards of a CME accrediting body, as authorized by the Accreditation Council for Continuing Medical Education (ACCME). Certified CME refers to CME activities that carry credit offered by the grantors of CME credit (the American Osteopathic Association (AOA), the American Academy of Family Physicians (AAFP), and the American Medical Association (AMA)). Continuing dental education is similarly accredited through the American Dental Association's Continuing Education Recognition Program (ADA CERP).

These commenters explained that accredited and certified continuing education speaker payments will generally not be made directly by an applicable manufacturer to a covered recipient, as this category suggests, due to the accreditation requirements. Some commenters suggested that these be reported in another ''indirect'' speaking engagement category. Conversely, other commenters recommended that this category be limited to accredited and certified continuing education payments, and that compensation for other speaking engagements should be described by other natures or payments.

Response: We appreciate the comments and agree that it is important that CMS clarify this category. We understand the importance of continuing medical education and discuss the requirements for reporting it generally in section II.B.1.k. of the final rule, dedicated to indirect payments or other transfers of value. We agree that given the title of this nature of payment category, which was set out in the statute itself, it should not include compensation for accredited or certified continuing education payments. However, we do not believe that all payments to physicians for serving as speakers at an accredited or certified continuing education program should be granted a blanket exclusion (as discussed in the indirect payment section), so we have added an additional nature of payment category for serving as a faculty or speaker at an accredited or certified continuing education event, at § 403.904(e)(2)(xv). This category, named ''compensation for

serving as faculty or as a speaker for an accredited or certified continuing education event,'' includes all accredited or certified continuing education payments that are not excluded by the conditions set forth in § 403.904(g)(1)(i) through (iii), and further discussed in section II.B.1.k. of this final rule. Additionally, we also renamed the category for direct compensation to include speaking engagements at unaccredited and non-certified continuing education events at § 403.904(e)(xiv). We recognize that not all payments or other transfers of value related to unaccredited and non-certified continuing education will be provided directly. Therefore, we retitled the category as ''compensation for serving as a faculty or as a speaker for an unaccredited and non-certified continuing education program.'' This renamed category includes all other instances when an applicable manufacturer provides compensation to a covered recipient for serving as a speaker or faculty at an unaccredited and non-certified education event, regardless of whether the payment was provided directly or indirectly. Finally, the nature of payment category for ''compensation for services other than consulting'' at § 403.904(e)(2)(ii) now explicitly includes payments or other transfers of value for speaking engagements that are not for continuing education.

We believe this reporting strategy appropriately separates accredited and certified continuing education from unaccredited and non-certified continuing education, so that consumers can better understand the nature of the payment received by a covered recipient. Accredited and certified continuing education that complies with applicable standards of the accrediting and certifying entities generally includes safeguards designed to reduce industry influence, so we believe that, when reportable (that is, when the payments or transfers of value do not meet the conditions delineated at § 403.904(g)(1)(i) through (iii)), payments or transfers of value made to support accredited and certified continuing medical education should remain in a distinct category from unaccredited or non-certified continuing education. We also believe that educational speaking engagements should be separated from all other speaking engagements, promotional or otherwise, to have separated them appropriately. Finally, we believe the renaming of the statutory nature of payment category for ''direct compensation for serving as a faculty or as a speaker for a medical education program'' to include indirect compensation as well, provides applicable manufacturers flexibility to describe payments or other transfers of value more accurately.

(4) Other

In the proposed rule, we added a nature of payment category, titled ''other,'' to serve as a catch all for payments or other transfers of value that do not fit into one of the listed natures of payment.

Comment: Many commenters recommended that CMS remove the proposed additional nature of payment category ''other.''

Response: We appreciate the comments and agree that an ''other'' category could dilute the usefulness of the nature of payment categories. Therefore, the final rule omits ''other'' category from the nature of payment categories at § 403.904(e). However, all payments or transfers of value from applicable manufacturers to covered recipients (other than those excluded under section 1128G(e)(10) of the Act) must be reported. Any payments or transfers of value that are not specifically excluded, must be reported and described based on the nature of payment categories included in the final rule. Applicable manufacturers are required to report each payment under the nature of payment category that most closely describes the payment; the absence of a nature of payment category that closely describes the payment does not constitute a basis for not reporting an otherwise reportable payment or other transfer of value. Failure to report such a payment may result in the imposition of a civil monetary penalty on the applicable manufacturer.

(5) Other Nature of Payment Categories

Although we did not address these categories in the proposed rule, we received comments requesting additional information on these categories and what CMS intends them to include. In the following sections, we have provided additional guidance on how we interpret the categories. Once again, this is not intended to define the categories, but rather to provide additional information for applicable manufacturers when considering the categories.

(A) Consulting Fees

This category is intended to include fees paid by an applicable manufacturer to a covered recipient for services traditionally viewed as consulting services. While we believe there is likely variation, we believe that consulting services are typically provided under a written agreement and in response to a legitimate need by the applicable manufacturer. Similarly, we believe there is often a connection between the competence of the covered recipient paid and the purpose of the arrangement, as well as a reasonable number of individuals hired to achieve the intended purpose.

(B) Compensation for Services Other than Consulting

This category is intended to capture compensation for activities or services that are not traditionally considered consulting services, but are provided by a covered recipient to an applicable manufacturer. As discussed in the section on direct compensation for serving as a faculty or as a speaker for a medical education program, this category should include payments or other transfers of value for speaking engagements that are not related to continuing education, such as promotional or marketing activities.

(C) Honoraria

We believe this category is similar to ''compensation for services other than consulting.'' However, honoraria are distinguishable in that they are generally provided for services for which custom prohibits a price from being set.

(D) Gift

This category is a general category, which will often include anything provided to a covered recipient that does not fit into another category. For example, the provision of small trinkets (above the minimum threshold) would need to be reported as a ''gift'' since they are not included in any other category. However, provision of tickets to a professional sporting event should not be reported as a ''gift'' since this transaction is better described by the nature of payment category ''entertainment'' even if the provision of the tickets was a gift.

(E) Entertainment

This category is intended to include, but is not limited to, attendance at recreational, cultural, sporting or other events that would generally have a cost.

(F) Travel and Lodging

This category includes travel, including any means of transportation, as well as lodging. As required in section 1128G(a)(1)(A)(vi)(VII) of the Act, the destination, including City, State and country must be reported.

(G) Education

We believe this category generally includes payments or transfers of value for classes, activities, programs or events that involve the imparting or acquiring of particular knowledge or skills, such as those used for a profession. As stated in the section on indirect payments or other transfers of value, we do not intend to capture the *attendees* at accredited or certified continuing education events whose fees have been subsidized through the CME organization by an applicable manufacturer (as opposed to payments for speakers at such events); however, we believe that any travel or meals provided by an applicable manufacturer to specified covered recipients associated with these events must be reported under the appropriate nature of payment categories.

(H) Royalty or License

This category includes, but is not limited to, the right to use patents, copyrights, other intellectual property and trade secrets, including methods and processes. We believe this may be pursuant to a written agreement and could entail various payment schedules (such as scheduled or milestones methods). Applicable manufacturers may report total aggregated payment amounts for payments made under a single agreement, in order to consolidate reporting.

(I) Current or Prospective Ownership or Investment Interests

We believe this category includes ownership or investment interests currently held by the covered recipient, as well as ownership interests or investment that the covered recipient has not yet exercised. Details on current ownership or investment interests is discussed in the section of the final rule dedicated to reporting ownership or investment interests of physicians.

(J) Grant

This category generally refers to payments to covered recipients in support of a specific cause or activity.

(6) Nature of Payment Categories

Based on the comments, and the discussion and justifications included in this section, we will allow applicable manufacturers to report the following categories in the nature of payment field to describe payments or other transfers of value. However, as stated previously, all payments or other transfers of value must be reported, unless excluded, even if they do not explicitly fit into one of the outlined nature of payment categories. Applicable manufacturers must select the nature of payment category that best describes the payment or other transfer of value. The nature of payment categories in the final rule are as follows:

- Consulting fee.
- Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program.
- Honoraria.
- Gift.
- Entertainment.
- Food and beverage.
- Travel and lodging (including the specified destinations).
- Education.
- Research.
- Charitable contribution.
- Royalty or license.
- Current or prospective ownership or investment interest.
- Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program.
- Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program.
- Grant.
- Space rental or facility fees.

(7) Assumptions Document

In order to monitor how applicable manufacturers were classifying payments or other transfer of value, we proposed that applicable manufacturers could submit along with their data a document describing the assumptions used when categorizing the natures of payments. We proposed that submission of the assumptions document would be voluntary and would not be made public. We explained that the documents could aid the agency in offering further guidance to applicable manufacturers regarding how natures of payment should be classified.

Comment: A few commenters questioned the CMS proposal to allow applicable manufacturers to submit an assumptions document in order to ensure consistency in the reporting and selection of categories. Many of these commenters supported the submission of the assumptions document; however, the commenters varied as to whether the assumptions documents should be mandatory. Some commenters recommended that it be mandatory, while others supported that it be voluntary. Additionally, the commenters also both supported and opposed the proposal not to make the assumptions document public. A few commenters expressed that the assumptions documents should not be published on the public Web site and should also not be subject to a Freedom of Information Act (FOIA) request. Conversely, other commenters recommended that even if the assumptions documents were not made public, they should be available to covered recipients upon request to help mitigate disputes.

Beyond the publication of the assumptions document, some commenters discussed the expected content for the assumptions document, as well as how CMS intends to use the documents. Regarding the content of the assumptions document, a few commenters recommended that applicable manufacturers may include other reporting assumptions and methodologies, beyond natures of payment, such as determining whether an interaction constitutes a payment or other transfer of value. Other commenters recommended that CMS create its own assumptions document for applicable manufacturers to use when characterizing payments or other transfers of value. Finally, a few commenters recommended that CMS clarify that it intends to review the submitted assumptions documents and does not plan to use them for purposes of prosecution for failure to report.

Response: We appreciate the comments, and given the support for the assumptions document, we are finalizing the voluntary submission of an assumptions document in this final rule. As discussed in the section of the preamble to this final rule on payments or other transfers of value (section II.B.1.F. of this final rule), applicable manufacturers may include in the assumptions document assumptions and methodologies other than only those employed when classifying nature of payment categories. Furthermore, applicable GPOs reporting under section 1128G(a)(2) of the Act may also submit an assumptions document. The assumptions document may include the applicable GPO's assumptions when categorizing nature of payment categories for any information submitted on payments or other transfers of value provided to physician owners or investors (as required in section 1128G(a)(2)(C) of the Act) or any other assumptions or methodologies the applicable GPO wishes to include.

After review of the comments, we continue to believe that submission of the assumptions document should be voluntary and that the contents of the assumptions documents submitted should not be made public. We believe that they will likely contain significant detailed information, which will not necessarily be consumer friendly, so it could be overwhelming on the public Web site. We encourage applicable

manufacturers to be as clear and specific as possible with regard to the information submitted within the assumptions document. If a statement within the assumptions document pertains to a particular section of the report, applicable manufacturers should explicitly refer to that section in the assumptions document. Additionally, we do not believe that we should provide the assumptions documents to covered recipients. This would be difficult for the agency to track and would greatly reduce the confidentiality of the documents. Applicable manufacturers may provide their assumptions document to covered recipients upon the request of covered recipients independently from CMS. To the extent an assumptions document is requested under the FOIA, we would follow our predisclosure notification procedures at 45 CFR 5.65(d) and seek the submitter's input on the applicability of FOIA Exemption 4, which protects trade secrets and commercial or financial information that is obtained from a person and is privileged or confidential.

The agency intends to carefully review the assumptions documents to determine whether we need to publish more detailed guidance to assist applicable manufacturers in classifying the nature of payment categories, or other assumptions or methodologies included in the assumptions document. Additionally, we intend to provide assistance to applicable manufacturers to help classify payments or other transfers of value and hope that such guidance will be useful. Finally, we do not intend to use the assumptions document for prosecution, but acknowledge that the reporting based on the assumptions would be open to prosecution. Other HHS divisions, the Department of Justice (DOJ), or the Office of the Inspector General (OIG) could request access to the documents as part of an audit or investigation into an applicable manufacturer or applicable GPO.

i. Research

We received numerous comments on our proposed methods for reporting and presenting research-related payments. We recognize that reporting payments or other transfers of value for research activities is extremely complicated, since many research activities include large payment amounts which are spread across numerous activities and parties, and acknowledge that our proposed method did not fully address this complexity. We understand the need for a simple and clear reporting process, which allows the agency to accurately present research payments to consumers. We appreciate the comments and have revised the system to try to improve the process and ensure that the research is reported in a manner that most accurately describes the research relationship. A summary of the comments and our finalized process are outlined in this section.

(1) Scope of Research

In the proposed rule, we proposed to limit the research category to bona fide research activities, including clinical investigations that are subject to a written agreement or contract between the applicable manufacturer and the organization conducting the research *and* a research protocol. We based this criteria on the method used to identify payments eligible for delayed publication.

Comment: We received a number of suggestions from commenters about which types of research payments should be reportable. Many commenters recommended including a definition of research and suggested many different definitions. Additionally, some commenters recommended that CMS provide information on what constitutes a research protocol or written agreement. These commenters stated that not all research has a ''research protocol'' and recommended that the agency interpret the term broadly or not require that one exist in order for a payment to be described as research. For example, clinical research for devices is often different from clinical drug research and does not require a research protocol. Finally, many commenters recommended that CMS exclude certain research-related payments from the reporting requirements altogether, such as payments related to pre-clinical research, indirect research, or research by Principal Investigators (PI) not practicing medicine, due to the importance of research-related relationships in developing new treatments and products.

Additionally, a few comments addressed how to handle payments that could conceivably be related to research, but do not meet the definition of research. In the proposed rule, we solicited comments on the preferred method for these payments and the comments were mixed. Some recommended that CMS create another nature of payment category for these payments (such as one titled ''other research''); others recommended that CMS require applicable manufacturers to report the payment in another category.

Response: We appreciate the comments and agree that we should provide additional information and clarification about what constitutes research and what research-related payments must be reported. Based on suggestions in the comments received, we have decided to define research based on the Public Health Service Act definition of research in 42 CFR 50.603; this definition defines research as: ''a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research and product development.'' We believe this definition includes pre-clinical research and FDA Phases I–IV research, as well as investigator-initiated investigations. We have finalized that payments reported as research should be made in connection with an activity that meets the definition. In addition, we agree that requiring both a written agreement or contract *and* a research protocol is limiting for some types research, so we are finalizing that if a payment falls within the nature of payment category for research, it only needs to be subject to a written agreement or contract *or* a research protocol. This may include an unbroken chain of agreements (instead of a single agreement between the applicable manufacturer and the covered recipient) which link the applicable manufacturer with the covered recipient because we understand that many applicable manufacturers use other entities such as contract research organizations (CROs) (as defined in 21 CFR 312.3(b)), or site management organizations (SMOs) to manage their clinical research activities. For example, agreements between an applicable manufacturer and a CRO, between a CRO and an SMO, and then between an SMO and a teaching hospital would be considered a continuous chain of agreements from the applicable manufacturer to a covered recipient and would be considered a research agreement.

Regarding reporting of research-related payments which do not meet the definition of research, applicable manufacturers should report using the other categories available. We believe that the categories are sufficiently broad to provide applicable manufacturers options; for example, we believe the grant category could be used to sufficiently describe some of the transactions.

We also seek to respond to comments about which research-related payments should be reportable. In general, we believe that any payments related to the definition of research discussed previously should be reportable. We

recognize that research is important and have allowed research to be reported in a manner that acknowledges its special role. Given this consideration, we do not believe we should further limit the scope of research payments to be reported. Many of the comments sought to limit the reporting of research related payment in significant ways, such as only reporting direct research. However, we believe Congress clearly intended research-related payments or other transfers of value to be included in the reporting requirements, based on the inclusion of ''research'' as a nature of payment, the statutory definition of ''clinical investigation,'' and the procedures for delayed reporting for certain research-related payments or other transfers of value. We believe that excluding payments or other transfers of value related to clinical research or indirect research from the reporting requirements would be inconsistent with the intent of Congress. We do agree that pre-clinical research is slightly different, so we have outlined reporting requirements tailored to its unique structure which are discussed more in this section.

Additionally, as explained in the section on covered recipients, we do not believe the statute limits the reporting requirements to licensed physicians who regularly treat patients, so we plan to require reporting of research payments to PIs who meet the definition of ''physician,'' even if they do not regularly treat patients. Finally, material transfers (such as provision of a protein) to a researcher for discovery collaboration does not need to be reported when not part of a commercial or marketing plan and precedes the development of a new product. We believe for the purposes of this regulation that due to the early stage of the research process, the transferred material does not have independent value.

(2) Reporting Research Payments

We also understand that research payments are unique and should be reported differently than other payments or other transfers of value. We proposed special rules to report research payments, including a rule to separate the classification of research payments to clarify whether the payment or other transfer of value went indirectly or directly to the covered recipient. When reporting payments or other transfers of value designated as research, we proposed that applicable manufacturers must report the payment or other transfer of value as either ''indirect research'' or ''direct research.'' Additionally, we proposed that the payment or other transfer of value (whether direct or indirect research) should be reported individually under the names and NPIs of physician covered recipients serving as principal investigators. For indirect payments, this included the physician covered recipient(s) serving as principal investigator(s) who would ultimately receive payments from the clinic, hospital, or other research institution, assuming the applicable manufacturer is aware of the identity of the principal investigator(s). Finally, we proposed that for both direct and indirect research, applicable manufacturers must report the entire payment amount for each research payment (whether to the covered recipient or research institution), rather than the specific amount that was provided to the covered recipient.

Comment: A significant number of comments addressed the method proposed for reporting research payments. While there was some support for our proposed methods, the majority of the commenters did not support it and recommended a new method. Many commenters stated that allocating 100 percent of the research payment to the physician PI would be misleading, even if the payment amount was not aggregated into the physician's total payments. Similarly, many commenters did not support reporting a single payment multiple times, which some commenters feared could lead to double counting of research payments. These commenters provided numerous recommendations for how to report and present research related payments. The most common recommendation was to report research in a separate reporting template, which would include a single line item for each payment. The payment would include both the entity paid (such as the research institution) and list the name of the principal investigator. There were some variations in the recommendations, including reporting only the amount the PI received and that the applicable manufacturer must control the selection of the PI; however, the majority of comments followed this basic process. A few commenters also requested that applicable manufacturers should be allowed to report context of research or additional information on the research payment. Finally, a few commenters recommended that research payments be presented separately on the public Web site to clearly delineate them as a research-related payment or other transfer of value.

Response: We appreciate the comments and agree that reporting of research-related payments should be more representative of the actual payment stream for research. Applicable manufacturers must report research-related payments that ultimately are paid, in whole or in part, to a covered recipient (physician or teaching hospital). We have finalized that applicable manufacturers must report research payments separately in a different template, since we will be requiring the reporting of modified information. Applicable manufacturers will not be responsible for indicating whether a payment was direct or indirect. We have adopted a procedure similar to the process outlined in many of the comments, where a single research payment is reported once and includes the entity paid, as well as the name of the principal investigator(s). Applicable manufacturers must report each research payment once as a single interaction. They must report the name of the individual or entity (regardless of whether it is a covered recipient) that received the payment for the research services, as well as the principal investigator(s). When reporting the entity or individual that received the payment, we intend for the applicable manufacturer to report the entity or individual that received the payment, either directly from the applicable manufacturer or indirectly through a CRO or SMO. We believe that the recipient of the payment could include individual principal investigators, teaching hospitals, nonteaching hospitals or clinics. We intend for the principal investigator(s) to include the individual(s) conducting the research or providing the services on behalf of the research institution.

As discussed regarding the reporting elements for all payments or other transfers of value, in order to better identify and match covered recipients, the same identifying information will be required to be reported for each PI meeting the definition of covered recipient.

The applicable manufacturer shall be required to report the following for each research-related payment that ultimately is paid, in whole or in part, to a covered recipient (physician or teaching hospital):

- Name of research institution/other entity or individual receiving payment (regardless of whether a covered recipient)

++ If paid directly to a physician covered recipient, list the individual's name, NPI, State professional license number(s) and associated State names for at least one State where the physician maintains a professional license, specialty, and primary business address of the physician(s).

++ If paid directly to a teaching hospital covered recipient, list name and primary business address of the teaching hospital.

++ If paid to a non-covered recipient (such as a non-teaching hospital or clinic), list name and primary business address of the entity.

- Total amount of research payment.
- Name of study.
- Name(s) of related covered drug, device, biological or medical supply (same requirements as for all payments or other transfers of value) and NDC (if any).
- Principal investigator(s) (including name, NPI, State professional license number(s) and associated States for at least one State where the physician maintains a professional license, specialty, and primary business address);
- Context of research (optional).
- ClinicalTrials.gov identifier (optional).

We believe reporting this information for each research payment will better capture the nature of the research relationship, creating a simpler reporting mechanism for the applicable manufacturers to report payments and allowing end users a more accurate understanding of the relationship. We believe the study name will provide information on the research topics, but we have also included an optional field allowing applicable manufacturers to provide additional contextual information on or the objectives of the research. We intend this to be used similarly to the additional context allowed for reporting all payments or other transfers of value. Additionally, we also will allow applicable manufacturers to provide the ClinicalTrials.gov Identifier to allow consumers the ability to obtain more information on the study from ClinicalTrials.gov. However, we recognize that not all research studies will be posted on ClinicalTrials.gov, so this category will be optional. Finally, this represents the information required to be reported for each research-related payment or other transfer of value, but the agency may identify other optional fields, such as information on publications related to the research, in order to provide additional information and background on the public Web site.

For pre-clinical research, we finalize slightly modified reporting requirements since such early stage research is often not connected to a specific product. We intend pre-clinical research to include laboratory and animal research that is carried out prior to beginning any studies in humans, including FDA's defined phases of investigation. For pre-clinical research, applicable manufacturers only have to report the name of the research institution, principal investigator(s) (including name, NPI, State professional license number(s), specialty and business address), and the total amount of the payment, so they do not need to report an associated product, or study name.

We are also finalizing guidelines for what should be included in the total research payment amount. The amount should include the aggregated amount of any payments for services included in the written agreement/research protocol. We envision that this would include the costs associated with patient care, including diagnostics, exams, laboratory expenses, time spent by health care professionals treating the patient and managing the study, and the provision of study drugs, devices, biologicals, and medical supplies or other in-kind items. The payment amount should not include any payments for activities which are separate or segregable from the written agreement or research protocol or are paid through a method different than that of the research. For example, payments made directly to a physician for serving on a study steering committee or data monitoring committee that are not a part of the larger research payment should be reported separately. Payments for medical research writing and/or publication would be included in the research payment, if the activity was included in the written agreement or research protocol and paid as a part of the research payment. In addition to research payments, we also believe that meals and travel should be reported separately (under the food and travel nature of payment categories) unless included in written agreement or research protocol and paid for through the large research contract.

We realize that reporting requirements for research will be somewhat different than the procedure outlined for other natures of payment, but we believe that this is appropriate for research-related payments or other transfers of value. As several comments pointed out, due to the flow of research payments from sponsor to research institution, an applicable manufacturer might not know the specific details or amounts of how the larger research payment was spent. We do not intend for applicable manufacturers to be required to itemize each research payment, since they are usually large payments obligated to general administration of the study and the applicable manufacturer may not be aware of the daily activities. Additionally, we do not require the reporting of payments to non-covered recipients that are not passed on to covered recipients. For example, if an applicable manufacturer paid separately for a non-covered recipient to travel to a meeting, then it would not need to be reported. However, if an applicable manufacturers paid separately for a covered recipient (regardless of whether the individual was a PI or not) to travel to a meeting, then the travel would have to be reported in the name of the covered recipient traveling.

When reporting research payments, we also acknowledge that research payments are generally different than other payments and may not represent a payment to the covered recipient. For physician covered recipients whom are paid by a third party and not directly by the manufacturer, we will list research studies separately from all other payments provided to the covered recipient. For teaching hospitals, we will publish all research payments which went to the hospital as a research institution. These will be listed separately from other payments to the hospital, but will include both the study amount and study name.

We believe that presenting research payments in this method reflects the fact that research payments are unique and do not necessarily represent a personal payment to physicians; however, it still allows for research payments to be reported as intended by Congress, but in a less burdensome way for applicable manufacturers. In light of the public comments received, we believe that the modifications represent a better, more accurate method of reporting research payments.

j. Exclusions

Section 1128G(e)(10) of the Act excludes specific types of payments or other transfers of value from the reporting requirements.

Comment: We received numerous comments on the exclusions section of the proposed rule. Many of the comments focused on the statutory exclusions and the explanations CMS provided in the proposed rule. Beyond these comments, we also received numerous recommendations for additional exclusion categories to be included in the final rule. The recommended exclusions covered numerous specific relationships between applicable manufacturers and covered recipients, some related to healthcare, such as paying a physician at an on-site clinic, whereas others did not, such as campaign contributions to physicians running for political office.

Response: We appreciate these recommendations, but do not believe that we have the statutory authority to add exclusions beyond what was outlined in the statute. The statute expressly provides the Secretary discretion to require the reporting of additional information of payments or other transfers or value, and ownership or investment interests, but it does not provide a similar authority to add exclusion categories. We have finalized our policy that the exclusions will be defined by their dictionary definitions, but plan to provide additional clarification in response to the comments in this section. We believe that some of the recommended exclusions could be included in some of the statutory exclusions, so we have provided additional information to clarify our interpretation of these categories.

(1) Existing Personal Relationships

In the proposed rule we stated that we did not intend to require reporting of purely personal transfers of value (for example, if one spouse, who works for an applicable manufacturer, gives a present to the other spouse who is a covered recipient), and we solicited comments on this proposal.

Comment: Many commenters supported our intention to exclude payments or other transfers of value between individuals who happen to have existing personal relationships and recommended that it be included as a listed exclusion. A few commenters also recommended specific requirements, such as to include relationships between family members, to limit to bona fide relationships or to mirror the Federal employee exemption.

Response: We appreciate the comments and do not intend existing personal relationships to be reported, so we have finalized this provision in § 403.904(i)(14).

(2) Payments or Other Transfers of Value of Less Than $10

Small payments or other transfers of value, which the statute defines as payments or other transfers of value less than $10, do not need to be reported, except when the total annual value of payments or other transfers of value provided to a covered recipient exceeds $100. As required by section 1128G of the Act, for subsequent calendar years, the dollar amounts specified will be increased by the same percentage as the percentage increase in the consumer price index (CPI) for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year. In the proposed rule, we proposed that applicable manufacturers should not report to CMS any payments or other transfers of value less than $10 individually and all small payments or transfers of value in the same nature of payment category should be reported as one total amount for that category. We believed this would simplify reporting for applicable manufacturers and prevent the reporting of payments less than $10 individually. Given the timing of this final rule, we have decided to begin increasing the de minimis thresholds for reporting in CY 2014, and retain the statutory de minimis thresholds ($10 and $100) for reporting in CY 2013. We believe this simplifies reporting for the first year of data collection by employing simple numbers as thresholds. Also because these were the statutory thresholds, we believe applicable manufacturers should be prepared to collect data and report using these thresholds for CY 2013.

Comment: We received various comments on small payments or other transfers of value. Some commenters indicated that our proposed method for reporting small payments together might (for some applicable manufacturers) be more difficult than reporting small payments individually; these commenters recommended that CMS allow applicable manufacturers discretion in their reporting mechanism. Some commenters also recommended that CMS not change the thresholds within a single reporting year. Beyond comments on reporting of small payments, many commenters also addressed the small payment or transfer of value exclusion more generally. Many commenters questioned the thresholds and indicated that they were too low and recommended various higher thresholds. Similarly, some commenters recommended that CMS consider methods within the statutory requirements to reduce the number of small payments being reported. Finally, many commenters supported CMS's proposal to not report food and beverages at conferences and indicated that CMS should extend this to other items provided at conferences (both above and below the $10 threshold).

Response: We appreciate the comments and agree that applicable manufacturers should have discretion when reporting small payments. We had proposed requiring applicable manufacturers to bundle payments in order to reduce burden, but we do not want to require that method if some applicable manufacturers actually believe it to be more burdensome. Therefore, we will finalize that applicable manufacturers have flexibility in reporting small payments. They may either report them individually or bundled with other small payments or other transfers of value in the same nature of payment category, as long as applicable manufacturers are reporting consistently and clearly indicating the method they are using. Additionally, we agree that the de minimis thresholds should not change within a reporting year and will be constant for the entire year. For example, for the entirety of data collection in 2014, the thresholds will be those adjusted based on CPI published in June 2013. We will report the new de minimis value with the reporting template for the next reporting year.

We appreciate the comments on the threshold for small payments and understand that they may be low for some stakeholders. Nevertheless, the thresholds were mandated by the statute, and we do not have discretion to change them. However, we recognize that we do not want the database to be overwhelmed by small payments. We have considered options for reducing the number of small payments, but we believe that we do not have authority to change the reporting requirements for small payments or other transfers of value.

Regarding reporting of payment or other transfers of value at conferences or similar events, we appreciate the comments and have provided additional guidelines expanding on the proposed rule. In general, we will finalize that these guidelines will apply to conference and similar events, as well as events open to the public. We believe that at events open to the public, it will be extremely difficult for applicable manufacturer to identify physician covered recipients. Therefore, we will finalize that small incidental items that are under $10 (such as pens and note pads) that are provided at large-scale conferences and similar large-scale events will be exempted from the reporting requirements, including the need to track them for aggregation purposes. While these small payments are excluded by statute, the $100 aggregate payment requirement generally requires the tracking of small payments in order to determine whether covered recipients received more than $100 annually. For these covered recipients, we believe it would be difficult for applicable manufacturers to track who receives these small items at conferences or similar events, due to the nature and disparate attendance at large-scale conferences or similar events. Additionally, this method is consistent with our decision to not require

reporting of food and beverage at large-scale conferences. We note that payments or other transfers of value of $10 or more (for calendar year (CY) 2013) need to be tracked and reported even when provided at large-scale conferences or similar events. We believe that if an applicable manufacturer is handing out an item above the threshold, they should be able to track who received the payment since it is a more significant transfer.

Finally, we will not be providing a standard template for reporting by entities that organize and oversee events and conferences. These event and conference vendors are not applicable manufacturers, so we do not believe we should have any contact with them or impose requirements on them. We recognize that applicable manufacturers and their vendors will need to devise business practices to meet the requirements; however, we believe that many of the interactions at large-scale conferences and similar events will not be reportable, so we do not believe this will be excessively burdensome.

(3) Educational Materials That Directly Benefit Patients or are Intended For Patient Use

In the proposed rule, we explained that this exclusion was limited to materials (including, but not limited to, written or electronic materials) and did not include services or other items. Additionally, we considered whether certain materials provided by applicable manufacturers to covered recipients for their own education, but which are not actually given to patients (for example, medical textbooks), should be interpreted as educational materials that ''directly benefit patients.''

Comment: Many commenters addressed this exclusion, particularly questioning the meaning of ''materials.'' A few commenters stated that ''materials'' should be interpreted more broadly to include ''programs, services, and items'' since many applicable manufacturers provide services and items to patients in order to support disease management or increase medication adherence. These items are generally provided to patients through covered recipients. Finally, a few commenters also asked for clarification on what form these materials needed to be in and whether overhead costs for educational materials, such as time and printing, were included in the exclusion.

Response: We appreciate the comments and agree that ''materials'' should be interpreted somewhat more broadly for purposes of this exclusion. We understand that patient education is important and recognize that it may take a form other than written material, especially in the device context. For example, a device manufacturer may give a physician an anatomical model to help explain to patients how a procedure would work. We agree that such an item, which is given to physicians for the purpose of educating patients, falls within the exclusion. Similarly, if a manufacturer provides educational materials to a physician on a flash drive to be distributed to patients, the flash drive would also be included in the exclusion. However, if the drive was provided as a gift alongside the materials, then it would have to be reported, since it was secondary to the materials. Similarly, we believe that overhead expenses, such as printing and time, should be included in the exclusion as long as they are directly related to the development of the materials, which directly benefit patients or are intended for patient use.

Comment: Numerous commenters questioned CMS's interpretation of ''directly benefit patients or are intended for patient use.'' These commenters had mixed reactions to CMS's proposed interpretation. Some recommended that all materials provided to educate physicians (such as textbooks or journals) should be included in the exclusion, since educating the physician benefits patients. Others suggested that these should not be included, since they do not benefit patients directly. Some commenters also recommended that materials that are used ''for or with'' patients, but not taken home (such as anatomical models or wall charts) should be included in the exclusion because they are intended for patient use. Finally, a few commenters recommended that all materials intended for patients should be included in the exclusion.

Response: We appreciate the comments and agree that additional clarification is required. We agree that items that are educational to covered recipients (such as medical textbooks and journal reprints), but are not intended for patient use are important for physicians; however, we do not believe that these materials fall within the statutory exclusion. Although these items may have downstream benefits for a patient, we believe they are not directly beneficial to patients, nor are they intended for patient use, as required by section 1128G(e)(10)(B)(iii) of the Act. Therefore, we will finalize that educational materials provided to covered recipients for their own education, but that do not ''directly'' benefit patients, do not fall within the exclusion and are therefore subject to the reporting requirements. Conversely, we have finalized that this exclusion does encompass materials, such as wall models and anatomical models which are ultimately intended to be used with a patient. In addition, we believe that pursuant to the statutory text, the exclusion is limited to educational materials only, and not marketing or promotional materials.

(4) Discounts and Rebates

Discounts and rebates for covered drugs, devices, biologicals, and medical supplies provided by applicable manufacturers to covered recipients are excluded from reporting under section 1128G(e)(10)(B)(vii) of the Act.

We did not receive any comments on this exclusion, so we have finalized it as proposed.

(5) In-Kind Items for the Provision of Charity Care

In the proposed rule, we defined ''in-kind items for the provision of charity care'' as items provided to a covered recipient for one or more patients who cannot pay, where the covered recipient neither receives, nor expects to receive, payment because of the patient's inability to pay. Any items provided by the applicable manufacturer to a covered recipient that meet the definition of in-kind items for the provision of charity care, are excluded from reporting. This does not include the provision of in-kind items to a covered recipient, even if the covered recipient is a charitable organization, for the care of *all* of the covered recipient's patients (both those who can and cannot pay). If a payment or other transfer of value is not an in-kind item and/or not for the provision of charity care, as defined, then the payment must be reported as required under section 1128G of the Act.

Comment: Many commenters provided recommendations on the charity care exclusion. These comments fell in two categories: first, on the interpretation of a patient's ability to pay, and second, on the interpretation of in-kind items. Regarding a patient's ability to pay, the commenters generally supported the proposed interpretation, but recommended that CMS provide additional clarification that a patient's ability to pay includes whether the patient can afford the copayment or coinsurance, but not the entire visit. Additionally, a few commenters recommended that ability to pay should be based on whether payment will be a significant burden to a patient. Regarding in-kind items, the

commenters discussed whether payments to a covered recipient and/or a third party should be excluded if used to support charities or other charitable activities, such as patient assistance programs. Finally, a few commenters advocated that this exclusion should be based on the mission of the organization receiving the items, rather than what actually happened to them, since it will be impossible for applicable manufacturers to track the uses of these items.

Response: We appreciate the comments and agree that an analysis of a patient's ability to pay should include whether the patient can afford his or her copayment or coinsurance and whether the patient has insurance to cover the care. We intend this exclusion to include in-kind items given to covered recipients to provide care to patients who are unable to pay, or for whom payment would be a significant hardship.

Finally, we do not intend applicable manufacturers to be responsible for tracking each individual item provided to a covered recipient to ensure it is provided to a patient unable to pay. We believe it is sufficient for the applicable manufacturer and covered recipient to agree in writing that the covered recipient will use the in-kind items only for charity care.

Secondly, we believe that the statutory text for this exclusion (section 1128G(e)(10)(B)(viii) of the Act) clearly states that the exclusion should only apply to ''in-kind items'' and not all payments, so we have finalized that only in-kind items will be included in the exclusion, which does not include financial support for charitable covered recipients. However, we recognize that some payments made to charitable third parties may at some point indirectly benefit a covered recipient. We believe that these payments or other transfers of value should be reported based on the reporting requirements for indirect payments or other transfers of value. However, we believe that charitable contributions made directly to or intended for a covered recipient should be reported as a charitable contribution.

(6) Product Samples

Even though this exclusion was not specifically discussed in the proposed rule, we received comments on the exclusion for product samples from section 1128G(e)(10)(B)(ii) of the Act which states that ''product samples that are not intended to be sold and are intended for patient use'' are excluded from the reporting requirements.

Comment: Many commenters recommend that CMS clarify the boundaries of the exclusion and interpret it widely to include samples beyond traditional drug samples, such as single use or disposable devices, demonstration devices, and evaluation equipment. A few commenters also recommended that the exclusion should include products used for research studies, as well as coupons and vouchers. Finally, a commenter stated that an applicable manufacturer may not know what actually happens to samples and should not be required to track them.

Response: We appreciate the comments and agree that further clarification is necessary. We believe that the statutory text is clear that this exclusion applies to products intended for patient use; therefore, any drug, device, biological or medical supply provided as a sample to a covered recipient that is intended for use by patients will be included in the exclusion. Given this interpretation, as long as single use or disposable devices, demonstration devices or evaluation equipment provided to a covered recipient are intended for patient use, they will be included in the exclusion. Otherwise, we believe these items may be excluded from the reporting requirements under the exclusions for short term loans, as explained in that section. In addition, we believe that products used for research studies should be included as a part of the larger research payment. Regarding coupons and vouchers, we believe they fall within the exclusion, so we have finalized that all coupons and vouchers for the applicable manufacturer's products that are intended for patient use to defray the costs of covered drugs, devices, biologicals or medical supplies will be included in this exclusion category. For the purposes of this rule, we believe such coupons and vouchers are materially similar to samples. Finally, we do not believe the applicable manufacturer should be responsible for tracking what actually happens to samples. Instead, we believe that as long as the applicable manufacturer and covered recipient agree in writing that the products will be provided to patients, which is commonplace in the industry, the provision of samples can be excluded.

(7) Short Term Loans

This exclusion was also not addressed in detail in the proposed rule; however we did receive some comments recommending clarifications. Section 1128G(e)(10)(b)(iv) of the Act excludes ''the loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient.''

Comment: A few commenters recommended that we include loans of a broad range of devices (including medical supplies) such as both covered and non-covered devices, as well as a short-term supply of disposable devices. Additionally, some commenters requested clarification on the timing of the 90-day loan period and what to report if the loan goes beyond 90 days. We also received a comment to shorten the loan period to 60 days.

Response: We appreciate the comments and agree that this exclusion can include a broad range of devices. We have finalized that this exclusion may include loans for covered devices, as well as those under development. We also have finalized that this will include a supply of disposable or single use devices (including medical supplies) intended to last for no more than 90 days. We believe that these products should be treated similarly to non-disposable devices and, therefore, should be included in the exclusion. However, we do not believe that applicable manufacturers should be allowed to provide an unlimited supply of these products and still fall within the exclusion, so we are establishing a 90-day supply as the limit. If an applicable manufacturer provides a specific disposable or single use device for more than 90 days (even if provided over multiple dates), the products provided beyond the 90-day supply will be subject to the reporting requirements.

For a single product the total number of days for the loan should not exceed 90 days for the entire year, regardless of whether the 90 days were consecutive. We believe that this aligns with the intention of the statute to limit the loan period to 90 days and not allow a new loan to start at the end of the previous loan period, thus avoiding the reporting requirements. In the event that the loan of a non-disposable device exceeds 90 days (for the entire calendar year), the applicable manufacturer should start reporting as if the loan began on day 91. We do not believe that reporting the prior 90 days as a payment or other transfer of value would greatly increase the payment value which would be misleading to consumers. Additionally, if a device is purchased within 90 days, the applicable manufacturer does not need to report the loan since the loan was less than 90 days. The loan period is statutorily defined, so we do not have the authority to lower it, but appreciate the input that 90 days should be more than sufficient for the loan period.

(8) Contractual Warranty

While this exclusion was not addressed in the proposed rule, we received a few comments on it. Section 1128G(e)(10)(B)(v) excludes ''items and services provided under a contractual warranty, including the replacement of a covered device, where he terms of the warranty are set forth in the purchase or lease agreement for the covered device.''

Comment: Some commenters recommended that CMS allow the exclusion to extend to items and services provided under a contractual warranty, regardless of whether or not the warranty period had expired. These comments stated that often applicable manufacturers grant the terms of a warranty even after the period has expired. Additionally, a few commenters recommended that the exclusion should include other product contracts, such as product sale agreements, maintenance service agreements, and technical support agreements. Finally, a few commenters also recommended that replacement products as a part of a product recall should be included in this category.

Response: We appreciate the comments and agree that it is not materially different for an applicable manufacturer to grant the terms of a contractual warranty before the period expires or afterwards. We have finalized that as long as the contract warranty specified the terms prior to expiration and the terms do not change, then the exclusions may extend to items and services provided outside the expiration period. We believe the exclusion should extend beyond the express time period of the warranty, since the warranty terms, and thus the relationship, are the same before or after the expiration period and it will be misleading to consumers to only include a portion of the relationships.

In addition, we agree that there are numerous other contractual agreements that are similar to a warranty agreement, but are not specifically excluded. We believe that service or maintenance agreements are so similar to warranty agreements that it may be difficult to consumers and applicable manufacturers to meaningfully separate. We also believe the replacement products in the case of a product recall are materially similar and should be included. Given the similarities, we have finalized that items and services provided under a contractual service or maintenance agreement will also be subject to the exclusion.

(9) Covered Recipient Acting as a Patient

While this exclusion was not addressed specifically the proposed rule, we received a few comments on it. Section 1128G(e)(10)(B)(vi) of the Act excludes ''a transfer or anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.''

Comment: A few commenters recommended that CMS include in this exclusion situations when a covered recipient is a subject in a research study.

Response: We appreciate the comments and agree that a covered recipients participating as a subject (and not in a professional capacity) in a research study is the same as being a patient and, should be included in the exclusion.

(10) Provision of Healthcare

Although the exclusion was not discussed in detail in the proposed rule, we did receive a few comments. Section 1128G(e)(10)(B)(x) excludes ''in the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan.''

Comment: A few commenters recommended that CMS clarify that this exclusion includes the provision of health care to both covered recipients and their families covered under the self-insured plan. Similarly, received few commenters discussed other situations, outside a self-insured plan when an applicable manufacturer may reimburse a physician for provision of health care services to employees.

Response: We appreciate the comments and agree that payments to covered recipients for services rendered to family members receiving care under a self-insured plan should also be excluded from the reporting requirements. Similarly, we believe that the provision of healthcare to employees should extend beyond that offered under a self-insured plan. We understand that applicable manufacturers, both self-insured and otherwise, may provide healthcare services to employees beyond traditional insurance. We believe that for the purposes of this exclusion there is little material difference between the provision of healthcare under a self-insured plan and provision of healthcare outside a self-insured plan. We have finalized that this category encompasses other situations, beyond a self-insured plan, when an applicable manufacturer makes a payment to a covered recipient as part of healthcare services provided to the manufacturer's employees or their family, such as at an on-site clinic or at a health fair.

(11) Nonmedical Professional

This exclusion was not specifically addressed in the proposed rule and we did not receive specific comments on it, and we have finalized it as proposed. Section 1128G(e)(10)(B)(xi) of the Act excludes ''in the case of a covered recipient who is a licensed nonmedical professional, a transfer of anything of value to the covered recipient if the transfer is solely for the non-medical professional services of such licensed nonmedical professional.''

(12) Civil or Criminal Action or Administrative Proceeding

Although this exclusion was not specifically addressed in the proposed rule, we did receive a few comments on it. Section 1128G(e)(10)(B)(xii) of the Act excludes ''in the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of a covered recipient with respect to a civil or criminal action or an administrative proceeding.''

Comment: A few commenters recommended that CMS clarify the exclusion to include specific legal proceedings or arrangements, such as legal defense, prosecution, settlement or judgment of a civil or criminal action and arbitration or other legal action.

Response: We appreciate the comments and agree that the agency can help clarify this exclusion. We will finalize that other specific legal relationships will be included in the exclusion. We believe that there are numerous legal proceedings that require physician involvement and we plan to exclude all of them, in order to allow for clear, consistent reporting requirements for applicable manufacturers, covered recipients, and consumers.

k. Indirect Payments or Other Transfers of Value Through a Third Party

Section 1128G(e)(10)(A) of the Act also excludes the reporting of payments or other transfers of value that an applicable manufacturer makes indirectly to a covered recipient through a third party where the applicable manufacturer is unaware of the identity of the covered recipient. However, any payment or other transfer of value provided to a covered recipient through a third party, whether or not the third party is under common ownership with an applicable manufacturer or operating in the U.S., must be reported if the

applicable manufacturer is aware of the covered recipient's identity.

In the proposed rule, we proposed that indirect payments are excludable when an applicable manufacturer is unaware of the identity of the covered recipient and explained that an applicable manufacturer is unaware of the identity if the applicable manufacturer does not know (as defined in § 403.902) the identity of the covered recipient. The definition of ''know'' in § 403.902 provides that a person, with respect to information, has actual knowledge of the information, acts in deliberate ignorance of the information, or acts in reckless disregard of the truth or falsity of the information. This standard is consistent with the knowledge standard set forth in many laws, including the False Claims Act, and we believed it is one with which many applicable manufacturers are already familiar.

Comment: Numerous commenters discussed when an applicable manufacturer should be required to report indirect payments to covered recipients made through a third party. Many commenters recommended additional interpretations to further clarify when an indirect payment is reportable. A few commenters recommended that all indirect payments should be excluded from the reporting requirements; however, some other commenters supported the reporting of indirect payments. Similarly, some commenters requested that payments or other transfers of value made through certain third parties, such as medical professional societies, be carved out of the third party reporting requirements such that payments to covered recipients made through these entities would not be reportable.

Many commenters did not advocate excluding all indirect payments, but instead recommended ways to limit which indirect payments would be reported. One common recommendation was to limit the reporting of indirect payments to those under control of the applicable manufacturer. Commenters described this concept in various ways, but generally suggested that reporting should be limited to when an applicable manufacturer has control of the selection of the recipient of the payment, and not merely when they are aware of the covered recipient's identity.

Another common comment was that indirect payments or other transfers of value should only be reported if they are at the request of or designated on behalf of a covered recipient. These commenters stated that this was the statutory intent for reporting indirect payments given the language requiring reporting of payments made at the request of or designated on behalf of a covered recipient to a third party recipient. A subset of these commenters recommended that in order for a payment to be reportable, the applicable manufacturer must notify both the covered recipient and the third party that the payment will be reported and receive concurrence that it is accurate. Finally, a few commenters recommended that the applicable manufacturer must require, instruct or direct the third party to provide a payment or other transfer or value (or a portion of one) to a covered recipient(s).

Response: We appreciate the comments and agree that CMS should consider ways to further clarify when an indirect payment or other transfer of value should be reported. In addition, we intend that this exclusion refers to both payments and other transfers of value, despite references in the proposed rule to only transfers of value.

We do not agree that all indirect payments or other transfers of value should be excluded from the reporting requirements. Section 1128G(e)(10)(A) of the Act states that the exclusion of indirect payments or other transfers made through a third party is limited to situations ''where the applicable manufacturer is unaware if the identity of the covered recipient.'' This indicates that indirect payments or other transfers of value where the applicable manufacturer *is aware* of the identity of the covered recipient must be reported, and only those where the applicable manufacturer is unaware of the identity are excluded. Moreover, we believe that excluding from the reporting requirements all payments made through a third party would create a significant loophole by allowing manufacturers to funnel payments through a third party and not report them; such a loophole would significantly undermine the intent of the reporting requirements. Additionally, we do not believe that we have statutory authority to carve out otherwise reportable indirect payments made through particular third parties, such as medical professional societies.

With regard to the recommendation that indirect payments should only be reported when under the control of the applicable manufacturer, we believe that controlling the selection of a recipient is different than being aware of the identity of the recipient. Congress based the exclusion on an applicable manufacturer being unaware of a covered recipient's identity, not on the applicable manufacturer lacking control over the selection of the covered recipient. Accordingly, we do not believe that Congress intended lack of control to be the basis for the indirect payment exclusion. Additionally, we believe that receiving a payment or other transfers of value from an applicable manufacturer could lead to conflicts of interest, even in the event that the applicable manufacturer does not directly control the selection of the covered recipient.

Similarly, we also do not believe that the statutory language suggests that indirect payments or other transfers of value are only reportable if they are made at the request of or designated on behalf of a covered recipient. The parenthetical reference in section 1128G(a)(1)(A) of the Act refers to payments or other transfers of value made to an entity or individual other than a covered recipient on behalf of or at the request of a covered recipient. We believe this situation is different from one in which a payment is provided to a third party and passed through to a covered recipient, as referenced in the exclusion in section 1128G(e)(10)(A) of the Act. In situations where a covered recipient requests that a payment or other transfer of value be provided to a third party, and the third party in turn provides the payment or other transfer of value to the covered recipient, the payment must be reported under the name of the covered recipient.

We agree with the comments that we should provide some guidance on when indirect payments must be reported. We understand that there are circumstances where an applicable manufacturer makes a payment to a third party, which will be passed indirectly to a covered recipient, unbeknownst to the applicable manufacturer. For example, an applicable manufacturer could make a payment to a consulting firm for professional services and the consulting firm incidentally employs a physician on the project. The applicable manufacturer's payment was ultimately transmitted, at least in part, to a physician covered recipient, but not because the applicable manufacturer directed that the payment be made to a specific physician, or to any physician at all. We believe that in these situations, it would be misleading to require reporting of the relationship, since the applicable manufacturer did not intend or expect that a covered recipient would receive any portion of the payment or other transfer of value.

In order to address this concern and clarify when an indirect payment must be reported, we have provided for the purposes of these regulations a definition of ''indirect payments or other transfers of value'' in § 403.902.

The definition states that an indirect payment or other transfer of value is one that an applicable manufacturer requires, instructs, or directs to be provided to a covered recipient, regardless of whether the applicable manufacturer specifies the specific covered recipient. For example, if an applicable manufacturer provided an unrestricted donation to a physician professional organization to use at the organization's discretion, and the organization chose to use the donation to make grants to physicians, those grants would not constitute ''indirect payments'' because the applicable manufacturer did not require, instruct, or direct the organization to use the donation for grants to physicians. The physician professional association could have used the donation for another purpose at its discretion. In this situation, the applicable manufacturer would not be required to report the donation, even if a portion of the payment or other transfer of value was ultimately provided to a covered recipient as a grant (or some other type of payment or other transfer of value). However, if an applicable manufacturer gave money to a medical professional society earmarked for the purpose of funding awards or grants for physicians, the awards or grants would constitute indirect payments to covered recipients and would be subject to the reporting requirements. In another example, an applicable manufacturer may provide a general payment to a clinic for one of its employed physicians to review materials. In this case, the applicable manufacturer directed that the payment be provided to a physician covered recipient, so it would constitute an indirect payment and would be a reportable indirect payment or other transfer of value.

Comment: A number of commenters recommended alternative definitions of ''aware.'' For example, many commenters recommended that we use a standard of ''actual knowledge'' or ''constructive knowledge,'' rather than the False Claims Act standard. Additionally, many commenters also discussed an applicable manufacturer's affirmative duty to investigate the identities of covered recipients. The commenters suggested that applicable manufacturers should not have an affirmative duty to determine the identity of a covered recipient, but that the proposed definition of awareness meant that applicable manufacturers would have an affirmative duty. These commenters stated that an applicable manufacturer would be in reckless disregard, if it knew that a payment or other transfer of value went to a covered recipient, but did not specifically know the identity of the covered recipient.

Similarly, some commenters also discussed the language in the proposed rule that attributes awareness of the identity of the covered recipient by an agent of the applicable manufacturer to the applicable manufacturer. Commenters both supported and opposed the proposal. Some of these commenters recommended that CMS provide additional information on how the agency interpreted ''agent.''

Finally, many commenters also recommended that CMS apply some sort of time restriction on the awareness requirement. The proposed rule did not specify whether there was a specific time period for awareness of the identity of the covered recipient, so the commenter requested clarification. Many of the commenters recommended that an applicable manufacturer must be aware of the identity of a covered recipient at the time of payment. Whereas, other comments provided slight variations, such as awareness at the time the payment is committed or agreed upon, but in general the majority of commenters focused on the time of payment.

Response: We appreciate the comments on alternative interpretations of the statutory tem ''unaware''; however, we have decided to finalize our proposed definition that an applicable manufacturer is ''unaware'' if it does not know the identity of a covered recipient, and that ''know'' means that the manufacturer has actual knowledge of the identity or acts in deliberate ignorance or reckless disregard of the identity. We appreciate the concerns about the knowledge standard, but we are concerned that the actual knowledge standard suggested by several commenters is too limiting. An actual knowledge standard could potentially allow applicable manufacturers to direct payments to a limited category or subset of individuals and avoid the reporting requirements by not knowing the names of the specific covered recipients and claiming a lack of actual knowledge. We believe that by clarifying that applicable manufacturers must only report indirect payments or other transfers of value that they direct or instruct third parties to pay to covered recipients, we will address some of the commenters' concerns about the broader knowledge standard. Therefore, if a payment meets the definition of an indirect payment or other transfer of value in § 403.902, then the payment can only be excluded from the reporting requirements if the applicable manufacturer did not ''know'' the identity of the covered recipient, as defined in § 403.902. However, we want to clarify that, for purposes of this rule only, we will not consider an applicable manufacturer to be acting in deliberate ignorance or reckless disregard of a covered recipient's identity in situations when the reason a payment or other transfer of value is being made through a third party is that the identity of the covered recipient remains anonymous. For example, an applicable manufacturer may hire a market research firm to conduct a double-blinded market research study, which includes paying physicians $50 for responding to a set of questions. The applicable manufacturer clearly intends a portion of the payment to be provided to physicians, but given that the reason for the third party's involvement is specifically to maintain the anonymity of the respondents and sponsor, we do not intend this to be considered a reportable indirect payment or other transfer of value.

We recognize that by finalizing the proposed definition, applicable manufacturers may still feel they have an affirmative duty to determine the identity of covered recipients. However, our intention with this definition is to prevent applicable manufacturers from directing payments to a discrete set of covered recipients whose identities the manufacturer may not actually know, but could easily ascertain. For example, we believe that a manufacturer that directs a third party to make payments to the top billing cardiologists in a certain city or the chiefs of staff of a certain class of hospitals should be required to report these payments, even though they do not have actual knowledge of the identities of such individuals. However, we do not require reporting of every payment that an applicable manufacturer makes through a third party that is ultimately provided to a covered recipient; rather, the intent is to require reporting of indirect payments where applicable manufacturers know or should know the identity of the covered recipients who receive them.

We appreciate the comments regarding awareness of an agent of an applicable manufacturer of the identity of a covered recipient; however, we have finalized the requirements as proposed. We understand that awareness by an agent is somewhat different than awareness of the applicable manufacturer, but believe the reporting of indirect payments in this situation is warranted. Otherwise, applicable manufacturers could structure their business model, so that

payments are funneled through an agent that selects the recipients. However, we do not intend the concept of an agent of the applicable manufacturer to be merely any third party with a connection to the applicable manufacturer. Instead, we intend the term to refer to legal agents acting on behalf of the applicable manufacturer.

Finally, we agree that applicable manufacturers should not be responsible for tracking and reporting indirect payments or other transfers of value indefinitely. However, we do not agree that the time period for awareness of the identity of the covered recipient should be limited to the time the applicable manufacturer made the payment to the third party. We are concerned that this would allow applicable manufacturers to funnel payments or other transfers of value to third parties, and thereafter direct them to specific covered recipients, thus potentially avoiding the reporting requirements. Additionally, we believe there are multiple dates which could be reported, such as the date the applicable manufacturer decides to make the payment, or the date the payment is sent to or received by the third party, making it difficult to standardize a policy. After reviewing the comments, we will finalize that for the purposes of this exclusion, an applicable manufacturer must be unaware of the identity of a covered recipient during the reporting year and the second quarter of the subsequent year following the transfer of the payment from the third party to the covered recipient. Therefore, if an applicable manufacturer becomes aware of the identity of a covered recipient on or before June 30th of the year following the year in which the payment is made by the third party to the covered recipient, then the payment or other transfer of value must be reported. For example, an applicable manufacturer makes a payment to a medical professional society in March 2013 with instructions to use the money to provide grants to physicians. This payment meets the definition of an indirect payment, since the applicable manufacturer earmarked the payment for the physician grants. The professional society selects and makes payments to the grantees in April 2013 and alerts the sponsoring applicable manufacturer to the grant recipients in June 2013. Since the applicable manufacturer became aware of the identity of the covered recipients receiving the grants during the reporting year in which the payment was made, the payment or other transfer of value must be reported. Similarly, if the payment was made in November 2013, and the professional society provided the names of the grantees to the applicable manufacturer in April 2014, the payment would be reportable as part of the applicable manufacturer's report for CY 2014.

In determining this standard, we sought a definite time period, since the applicable manufacturer may not know the selection and payment process of the third party making the actual payment to the covered recipient. We also sought a uniform cut off point for all payments or other transfers of value in a reporting year, rather than a rolling time period, which would be based on the date of payment (such as 6 or 12 months after the date of payment). We believe a rolling date would be difficult due to the reasons outlined previously regarding inconsistency in the date of payment, as well as due to operational difficulties for both CMS and applicable manufacturers to track the awareness standard for each payment or other transfer of value. In order to set a date which applied to an entire year, we needed to set a date beyond the end of the reporting calendar year (December 31), which allows some time for indirect payments or other transfers of value made late in the year to be finalized. However, we did not want to set a time period which was too long and would require applicable manufacturers to report indirect payments that were made several years prior. We believe that two quarters beyond the end of the payment reporting year is sufficient for payments or other transfers of value made late in the year.

Comment: Several commenters questioned the process for reporting indirect payments, which was not addressed in detail in the proposed rule. A few commenters suggested that applicable manufacturers should be required to label all payments as direct or indirect and report the entity paid. Similarly, some commenters recommended that CMS clarify the amount of information that a third party should be required to provide to applicable manufacturers regarding indirect payments or other transfer of value. These commenters expressed that it would be burdensome for third parties to provide detailed information to applicable manufacturers regarding the recipients of payments made using the manufacturer's funding. Finally, a few commenters also inquired about the process for reporting payments when multiple applicable manufacturers contribute to a specific payment or other transfer of value. For example, multiple applicable manufacturers may fund a single speaker.

Response: We appreciate the comments and agree that providing more detail is necessary. However, we do not believe it is necessary to significantly change the reporting requirements for indirect payments. Given the unfavorable comments submitted regarding the proposal to classify research payments as direct or indirect, we believe that it would be similarly confusing to classify *all* payments or other transfers of value as either direct or indirect. Additionally, we do not believe it is necessary or appropriate for CMS to provide any requirements on the information third parties should or should not report. Applicable manufacturers will need to work with the third parties through which they make payments to covered recipients to ensure that the third parties are taking the appropriate steps to track the indirect payments. We recognize that this will, in some cases, require the third parties to put in place new tracking systems, but we believe that in many cases, such tracking systems already exist. For example, we believe that physician professional societies generally keep track of the physicians to whom they provide industry-funded grants and may not need to put new accounting systems in place in order for applicable manufacturers to be able to comply with the reporting requirements of this rule. Finally, we seek to clarify the situation when multiple applicable manufacturers provide a payment or other transfer of value to a covered recipient through a third party. We intend to allow for flexibility because we want to ensure that no payment or other transfer of value is captured twice. Applicable manufacturers and third parties may work together to determine the best method for reporting the payment or other transfers of value, as long as the payment or other transfer of value gets reported. We believe payments or other transfers of value made through a third party to a covered recipient using funds from multiple applicable manufacturers will be limited, since the companies will be required to report only those payments or other transfers of value directed to covered recipients and not unrestricted, non-earmarked payments.

Comment: Numerous commenters questioned the reporting on indirect payments or other transfers of value for education, particularly accredited or certified continuing education (both CME and continuing dental education). A large number of these commenters recommended that accredited or certified continuing education payments

to speakers (and payments for supporting materials) should not be reported because there are safeguards already in place, and they are not direct payments or other transfers of value to a covered recipient. Many of these commenters also stated that requiring that the reporting of payments or other transfers of value related to continuing education would be detrimental to continuing education and would reduce the funding for and attendance at continuing education programs. Additionally, some of these commenters also strongly indicated that they believe that Congress did not intend to require applicable manufacturers to report payments related to accredited or certified continuing education programs. However, we did receive some comments supporting the reporting of accredited or certified continuing education-related payments or other transfers of value, particularly when the sponsor provides suggestions to the CME vendor for potential faculty or speakers at a CME program. No commenters recommended that payments made to subsidize the costs of attendees of continuing education programs (as opposed to payments for faculty or speakers) should be reported.

Beyond accredited or certified continuing education, these comments were mixed on whether unaccredited and non-certified speaking engagements should be reported. A few commenters also addressed other types of education, such as Risk Evaluation and Mitigation Strategies (REMS), suggesting that since they were required by FDA, sponsorship of REMS education should be exempted from the reporting requirements.

Response: We appreciate the comments and agree that industry support for accredited or certified continuing education is a unique relationship. The accrediting and certifying bodies, including ACCME, AOA, AMA, AAFP, and ADA CERP, and the industry standards for commercial support, create important and necessary safeguards prohibiting the involvement of the sponsor in the educational content. However, we believe that even with this separation, the sponsor may still influence the selection of faculty by offering suggestions to the accredited or certified continuing education provider; although the continuing education provider may not be required to follow these suggestions, we believe that it may often be impossible to distinguish when a suggestion is influential and when it is not.

We have finalized at § 403.904(g)(1) that an indirect payment made to a speaker at a continuing education program is not an indirect payment or other transfer of value for the purposes of this rule and, therefore, does not need to be reported, when all of the following conditions are met: (1) The program meets the accreditation or certification requirements and standards of the ACCME, AOA, AMA, AAFP or ADA CERP; (2) the applicable manufacturer does not select the covered recipient speaker nor does it provide the third party vendor with a distinct, identifiable set of individuals to be considered as speakers for the accredited or certified continuing education program; and (3) the applicable manufacturer does not directly pay the covered recipient speaker. We believe that when applicable manufacturers suggest speakers, they are directing or targeting their funding to the speakers, so these payments will be considered indirect payments for purposes of this rule. Conversely, when they do not suggest speakers, they are allowing the continuing education provider full discretion over the CME programming, so the payment or other transfer of value will not be considered an indirect payment for purposes of these reporting requirements. Additionally, since industry support of CME programs that meets all three requirements discussed previously will not be considered indirect payments or other transfers of value for the purposes of reporting, the awareness standards for indirect payments are not applicable to such support. We believe that this approach will greatly reduce the number of payments to speakers at accredited or certified continuing education programs that must be reported. Applicable manufacturers will not be responsible for reporting payments made to CME vendors that are used to subsidize attendees' tuition fees for continuing education events. However, as explained in the discussion of the nature of payment categories, payments or other transfers of value associated with attendance of an event (such as travel and meals) must be reported as required.

With regard to unaccredited and non-certified education, we believe that since this type of education program does not require the same safeguards as an accredited and certified program, payments or transfers of value should be reported as required for any other payment or other transfer of value. If the payment or other transfer of value is made indirectly, it will be subject to the same reporting requirements for all indirect payments. The details for how to report both accredited or certified, and unaccredited or non-certified continuing education payments or other transfers of value are discussed in section II.B.1.h. of this final rule, dedicated to nature of payment categories.

Finally, we do not agree with comments that payments related to REMS with elements to assure safe use that require prescriber education should have a blanket exclusion from the reporting requirements. We recognize that REMS are required by FDA for some prescription drug products to ensure that the benefits of a drug outweigh the risks and that REMS often requires a sponsor to inform or educate health care providers about the risks associated with a product. However, we believe that payments made in connection with prescriber education required by REMS should be reportable on the same basis as other education payments. For example, if a sponsor directs the choice of a program speaker, or pays for covered recipients' meals or transportation to a REMS educational program, such payments would be reportable. However, applicable manufacturers are not required to report the provision of written materials that have been approved by FDA for distribution to physicians, such as Dear Healthcare Provider letters. Other REMS educational materials may be excluded if they fall within the exclusion for materials intended for patient use described in § 403.904(i)(4).

2. Reports on Physician Ownership and Investment Interests Under Section 1128G(a)(2) of the Act

Section 1128G(a)(2) of the Act requires applicable manufacturers, as well as applicable GPOs, to report to the Secretary, in electronic form, certain information concerning ownership and investment interests held by physicians or their immediate family members in such applicable manufacturers and applicable GPOs, and payments or other transfers of value to such physician owners or investors. In the proposed rule, we proposed that applicable GPOs were only required to report under section 1128G(a)(2) of the Act.

Comment: A few commenters suggested that Congress intended applicable GPOs to report under section 1128G(a)(1) of the Act, as well as under section 1128G(a)(2) of the Act. These commenters supported their interpretation with the introductory language of section 1128G(a)(2) stating that ''[i]n addition to the requirement under paragraph (1)(A)'' regarding reporting of payments to covered recipients, applicable manufacturers and applicable GPOs must report information regarding physician ownership and investment interests.

Response: We appreciate the comment but do not agree that applicable GPOs are required to report under section 1128G(a)(1) of the Act. While the phrasing in section 1128(a)(2) could be phrased more clearly, we do not believe it suggests that applicable GPOs need to report under both sections. Applicable GPOs are not mentioned in section 1128G(a)(1) at all, indicating that Congress did not intend for them to be subject to the requirements of that section. Additionally, other sections of the statute, such as the definition of payment or other transfer of value (section 1128G(e)(10) of the Act), only refer to applicable manufacturers when discussing payments or other transfers of value separately from ownership of investment interests.

a. Reporting Entities

(1) Applicable Manufacturers

Section 1128G(a)(2) of the Act includes applicable manufacturers as defined for section 1128G(a)(1) of the Act, as entities subject to the reporting requirements in section 1128G(a)(2) of the Act.

(2) Applicable Group Purchasing Organizations

Section 1128G(a)(2) of the Act also includes applicable GPOs as entities required to submit reports on physician ownership or investment interests; these reports are also required to include payments or other transfers of value provided to the applicable GPO's physician owners or investors. Section 1128G(e)(1) of the Act defines ''applicable group purchasing organization'' as ''a group purchasing organization (as defined by the Secretary) that purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply, which is operating in the United States, or in a territory, commonwealth or possession of the United States.''

We proposed to define ''applicable GPOs'' as an entity that: (1) operates in the United States, or in a territory, possession or commonwealth of the United States; and (2) purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, and not solely for use by the entity itself.

We proposed that the definition will not include entities that buy covered drugs, devices, biologicals, or medical supplies solely for their own use, such as some large practices or hospitals (including those owned by physicians). Rather, it is our intent to capture entities (including physician-owned entities) that purchase, arrange for or negotiate the purchase of covered drugs, devices, biologicals, or medical supplies for resale or distribution to others. Additionally, we also interpreted the statute to encompass not only more traditional GPOs that negotiate contracts for their members, but also entities that purchase covered drugs, devices, biologicals, and medical supplies for resale or distribution to groups of individuals or entities. These interpretations would include, for example, physician owned distributors (PODs) of covered drugs, devices, biologicals, and medical supplies.

Comment: A number of commenter supported the definition of ''applicable GPOs,'' particularly the inclusion of PODs. However, some commenters suggested revisions to the definition in order to capture additional PODs. For example, these comments included removing the reference to ''group'' in the definition, as well as limiting the exclusion for entities that purchase the products for their own use to only those entities that are the end users of the device based on billing under the same provider or supplier number as the entities that purchased the product. The commenters suggested that this would capture both fee-based and buy-and-sell POD models. Finally, a few commenters recommended that CMS issue a few clarifications, including allowing reselling in case of shortages and explicitly including commonly owned entities purchasing together as ''own use.''

Response: We appreciate the comments, but do not agree with the recommended changes to the definition to include additional PODs. While we appreciate the need to include as many PODs as possible, we are concerned that removing the word ''group'' from the definition would be contrary to the statutory phrase ''group purchasing organization'' which clearly implies that in order to be a GPO, the entity must be purchasing for a group. Therefore, we are not going to remove the word ''group'' from the definition. We are also concerned that hospitals and large group practices may not always purchase under the same provider or supplier number with which they bill, making it difficult to determine the end user by billing number. Therefore, we will not be changing the language in the definition to require use of the same provider or supplier number. Based on these considerations, we have decided to finalize the proposed definition. We recognize that this definition may not include every POD model; however, we intend for it to capture as many PODs as possible, while still aligning with the statutory language. Finally, we do not intend our definition to apply to rare and circumstantial resale of a product in response to a documented drug shortage. Similarly, we believe that bulk purchasing of covered products for commonly owned entities, which will be used only by those entities, would be considered ''own use.''

b. Physician Owners or Investors

Section 1128G(a)(2) of the Act differs from section 1128G(a)(1) of the Act in that section 1128G(a)(2) of the Act does not use the term ''covered recipient'' as defined in 1128G(e)(6) of the Act, which explicitly excludes payments or other transfers of value to employees of an applicable manufacturer from the reporting requirements. Instead, section 1128G(a)(2) of the Act uses the term ''physician'' as defined in section 1861(r) of the Act. Based on this definition of ''physician,'' we proposed that the requirement to report physician ownership and investment interests includes any physician, regardless of whether the physician is an employee of the applicable manufacturer or applicable GPO. We did not receive any comments on this interpretation, and we will finalize it.

Additionally, as required by statute, ownership and investment interests of immediate family members of physicians must also be reported under this provision. In the proposed rule, we defined immediate family member as one of the following (as defined for purposes of section 1877(a) of the Act at 42 CFR 411.351):

- Spouse.
- Natural or adoptive parent, child, or sibling.
- Stepparent, stepchild, stepbrother, or stepsister.
- Father-, mother-, daughter-, son-, brother-, or sister-in-law.
- Grandparent or grandchild.
- Spouse of a grandparent or grandchild.

In the proposed rule, we also stated that in cases when the ownership or investment interest is held by an immediate family member of a physician, applicable manufacturers and applicable GPOs should report not only the required information for the physician, but also that the ownership or investment interest is held by an immediate family member of the physician. We considered whether to require the reporting of the immediate family member's relationship to the physician, as well as the immediate family member's name, but did not propose to require it.

Comment: A few commenters recommended that ownership or investment interests held by immediate family members of physicians should not be reported at all. Similarly, a few other commenters advocated that CMS employ a narrower definition of ''immediate family member.''

Response: We appreciate the comments; however, both the requirement to report ownership or investment interests of immediate family members of physicians, as well as the proposed definition of immediate family member, are required by statute. Section 1128G(a)(2) requires the reporting of ownership or investment interests held by an immediate family member of a physician and states that ''immediate family member'' is defined as it is for purposes of section 1877(a) of the Act, which is codified at 42 CFR 411.351. Given the statutory requirements, we have finalized the definition as proposed.

Comment: Many commenters supported *not* reporting the name and relationship of the immediate family member. However, a few commenters suggested that applicable manufacturers should not be required to report the name or relationship of immediate family members, but applicable GPOs should be required to report the information. Additionally, some commenters requested that CMS clarify expectations for how applicable manufacturers and applicable GPOs should obtain ownership or investment interest information. A few commenters also recommended that CMS should not require physicians to disclose this information and applicable manufacturers may rely on the representations by owners or investors regarding immediate family members. Finally, a few commenters recommended that in the event that multiple family members hold an ownership or investment interest in a specific entity, then the applicable manufacturer or applicable GPO should only report the ownership or investment interest in aggregate.

Response: We appreciate the comments and agree that applicable manufacturers and applicable GPOs should not report the name and relationship of immediate family members of physicians holding ownership or investment interests in such entities. However, we do not agree that this standard should be applied differently for applicable manufacturers and applicable GPOs since we believe the privacy for immediate family members is the same regardless of the entity at issue.

Regarding the requirements for obtaining information on ownership or investment interests, we have revised the definition to help clarify situations when the applicable manufacturer or applicable GPO does not know that a reportable ownership or investment interest exists. We do not have the authority to require physicians or owners or investors to report this information; however, we believe that an applicable manufacturer or applicable GPO may inquire about these relationships. These situations are discussed more fully in the section on the definition of ''ownership or investment interests.''

Finally, we also agree that applicable manufacturers and applicable GPOs may report a specific ownership or investment interest in aggregate across multiple family members. Since we are finalizing that applicable manufacturers and applicable GPOs do not need to report the name or relationship for an immediate family member holding an ownership or investment interest in such entity, we do not believe the reported interests need to be on the individual level and instead can be aggregated across multiple immediate family members. However, we intend that applicable manufacturers and applicable GPOs can only aggregate interests when multiple immediate family members have ownership or investment interests with the same terms (as reported pursuant to § 403.906(b)(5)) and the value reported includes the total value of all the immediate family member's interests.

c. Ownership or Investment Interests

We proposed to define an ownership or investment interest in an applicable manufacturer or applicable GPO in a similar manner as in the physician self-referral regulation (42 CFR 411.354(b)). Specifically, we proposed to define an ownership or investment interest as one that may be direct or indirect, and through debt, equity, or other means. We further proposed that ownership or investment interest includes, but is not limited to, stock, stock options (other than those received as compensation, until they are exercised), partnership shares, limited liability company memberships, as well as loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property of revenue. As required by statute, we proposed that an ownership or investment interest shall not include an ownership or investment interest in a publicly traded security or mutual fund, as described in section 1877(c) of the Act. Additionally, we proposed that ownership or investment interest must not include the following:

- An interest in an applicable manufacturer or applicable GPO that arises from a retirement plan offered by that applicable manufacturer or applicable GPO to the physician (or a member of his or her immediate family) through the physician's (or immediate family member's) employment with that applicable manufacturer or applicable GPO;
- Stock options and convertible securities received as compensation, until the stock options are exercised or the convertible securities are converted to equity;
- An unsecured loan subordinated to a credit facility.

Comment: Some commenters recommended that CMS only require that applicable manufacturers and applicable GPOs report direct ownership or investment interests, rather than both direct and indirect interests. However, the commenters also recommended a few limitations in the event the agency decided to require reporting of indirect ownership or investment interests. These recommendations included setting a minimum threshold amount for ownership interests, following the knowledge requirements in the physician self-referral regulation, and requiring that the physician has sole control of the interest. Beyond indirect ownership interests, a few commenters also recommended that CMS require reporting of stock options as ownership or investment interests when they are granted, rather than only when exercised. Similarly, a few commenters recommended that CMS not distinguish between ownership or investment interests arising from a retirement plan and stock options once exercised.

Response: We appreciate the comments. However, we do not agree that applicable manufacturers and applicable GPOs should only report direct ownership or investment interests. Section 1128G(a)(2) of the Act requires that applicable manufacturers and applicable GPOs report ''any ownership or investment interest * * * held by a physician.'' We believe that ''any ownership or investment interest'' encompasses both direct and indirect interests, since indirect ownership or investment interests are also true interests. However, we do agree that there should be some limitation on indirect ownership or investment interests. We appreciate the comments on ways to limit reporting of indirect ownership or investment interests. We believe that limiting ownership or investment interests to those when the

physician has sole control and right to receive the proceeds is too narrow. We believe this will eliminate a significant number of ownership or investment interests, greatly reducing those reported. Similarly, we believe that setting a threshold for indirect ownership or investment interest creates an incentive to structure relationships to remain below the threshold. However, we do understand that there should be some limitations. We have decided to finalize the recommendation that aligns with the physician self-referral rule in that applicable manufacturers and applicable GPOs will not have to report ownership or investment interests held by physicians or their immediate family members if they did not know about such interests. We agree that this limitation is warranted, since it is impossible for an applicable manufacturer or applicable GPO to report an indirect ownership or investment interest that is unknown to it. Additionally, we believe that many stakeholders are already familiar with this standard from the physician self-referral regulation. Therefore, we have finalized that applicable manufacturers and applicable GPOs do not have to report indirect ownership or investment interests held by physicians or immediate family members of physicians about which they do not know (as defined for the purposes of this rule).

Finally, we understand the concerns regarding stock options received as compensation and requiring reporting of options when granted, rather than when exercised. However, we believe that stock options before they are exercised are traditionally considered compensation, rather than an ownership or investment interest, so we do not believe that we should require them to be reported as held ownership or investment interests. This is consistent with the definition in the physician self-referral regulation. However, we note stock options will need to be reported when granted under sections 1128G(a)(1) and 1128G(a)(2)(C) of the Act as a payment or other transfer of value. Reporting under sections 1128G(a)(1) and 1128G(a)(2)(C) may not include all stock options that are granted to physicians. For example, stock options that are granted to a physician who is an employee of the applicable manufacturer and is not already an existing owner or investor of that entity would not be reported; however, we believe reporting under sections 1128G(a)(1) and 1128G(a)(2)C) will capture a significant portion of stock options when granted.

d. Physician Ownership or Investment Report Content

Under section 1128G(a)(2) of the Act, applicable manufacturers and applicable GPOs are required to report information about each ownership or investment interest held by physician owners or investors (or their immediate family member(s)).

As required in section 1128G(a)(2) of the Act, we proposed that the applicable manufacturer or applicable GPOs should report the name, address, NPI, and specialty of the physician owner or investor, as well as the dollar amount invested and the value and terms of the ownership or investment interest. Section 1128G(a)(2)(C) of the Act requires the reporting of ''[a]ny payment or other transfer of value provided to a physician holding such an ownership or investment interest (or to an entity or individual at the request of or designated on behalf of a physician holding such an ownership interest) * * *'' Applicable manufacturers and applicable GPOs must report all the information required in section 1128G(a)(1)(A) of the Act for those physicians who hold ownership or investment interests in such entity. With regard to reporting payments and transfers of value to physician owners or investors, we proposed that applicable manufacturers and applicable GPOs follow the procedures outlined in this preamble for reporting payments and other transfers of value.

We also noted that there was some overlap between the requirements for reporting payments or other transfers of value and reporting ownership or investment interests. In order to help manage the overlap, we proposed that applicable manufacturers submit one report for all their payments and other transfers of value and another for all their physician ownership or investment interests. To comply with section 1128G(a)(2)(C) of the Act, we proposed that applicable manufacturers report the payments or other transfers of value provided to physician owners or investors (regardless of whether the physician owner is a covered recipient) in the report for payments and other transfers of value, but should note that the covered recipient receiving the payment or other transfers of value is a physician owner or investor.

Since applicable GPOs are not subject to the reporting requirements in section 1128G(a)(1) of the Act, we believe there is less of a potential for duplicative reporting. However, we proposed that when an applicable GPO has payments or other transfers of value to report for physician owners or investors, the applicable GPOs should use the data elements outlined in section II.B.1.f. of the final rule on payments and other transfers of value report contents.

Comment: A few commenters discussed the content of physician ownership or investment interest reports. The commenters specifically recommended that CMS not require the reporting of the ''terms'' of the ownership or investment interest.

Response: We appreciate the comments. However, we are unable to waive reporting of the terms of an ownership or investment interest, since it is a statutory requirement. Because we did not receive any comments on other aspects, we will finalize these provisions to align with the reporting requirements for payments or other transfers of value reports to the extent the requirements overlap. For example, applicable manufacturers and applicable GPOs should report both physician NPI and State professional license number(s) for at least one State where the physician maintains a license (including the name of the applicable State) to ensure that the agency is able to attribute ownership and investment interests to the appropriate physician. Similarly, requirements for reporting name, primary business address and specialty should also be the same as described for reporting payments or other transfers of value. Finally, as described in the section on the assumptions document, both applicable manufacturers and applicable GPOs may submit an assumptions document including information on their assumptions and methodologies when reporting payments or other transfers of value, or ownership or investment interests.

Comment: We also received a few comments concerning the potential for duplicative reporting due to the overlap between the two sections. The comments requested clarification of the proposed rule but did not have any specific recommendation or advocate any particular changes.

Response: We appreciate the comments and seek to clarify as much as possible; however, we have finalized these provisions as proposed. Applicable manufacturers must report all payments or other transfers of value to covered recipients and physician owners or investors, including the provision of ownership and investment interests. In the event that a physician receives an ownership or investment interest in a given year, an applicable manufacturer should report it as a payment or other transfer of value (under section 1128G(a)(1) of the Act), as well as a standing ownership or

investment interest (under section 1128G(a)(2) of the Act).

Additionally, an individual may be both a covered recipient and a physician owner or investor, so an applicable manufacturer should only report a payment or other transfer of value once, regardless of whether the individual is a covered recipient, a physician owner or investor, or both. The payment or other transfer of value and all the additional required information must be reported in the ''payments or other transfers of value'' reporting template; however for physician owners or investor (regardless of whether the physician is a covered recipient) the applicable manufacturer should mark that that payment or other transfer of value was provided to a physician owner or investor. All payments or other transfer of value should only be reported once regardless of whether it is required to be reported under section 1128G(a)(1) and/or section 1128G(a)(2)(C) of the Act.

C. Report Submission and Review

The statute requires the Secretary to establish procedures for applicable manufacturers and applicable GPOs to submit the required information and for the Secretary to make such information submitted available to the public. We recognize that these regulations require applicable manufacturers and applicable GPOs to collect and submit large amounts of new data, so we have tried to finalize flexible processes for data collection and submission. However, we also recognize that in order to accept and aggregate the data effectively and efficiently, there needs to be system standardization.

1. Prior to Submission

In the proposed rule, we considered that prior to submission of data to CMS, applicable manufacturers and applicable GPOs would provide each covered recipient or physician owner or investor with information regarding the information that the applicable manufacturer plans to report to CMS on the covered recipient's or physician owner or investor's behalf. While we did not propose to require this type of pre-review, we recommended that applicable manufacturers and applicable GPOs provide it.

Comment: Several commenters supported the pre-submission review. However, the commenters were divided over whether to require it or leave it voluntary. Many commenters stated that there simply was not time between the end of the data collection year and the data of submission to facilitate the review; whereas some commenters recommended it, stating it would greatly reduce disputes and inaccuracies in the data.

Response: We appreciate the comments and agree that pre-submission review would help ensure the accuracy of the data. However, we have finalized that CMS will not administer or manage a pre-submission review process and will not make it mandatory. We recommend that applicable manufacturers voluntarily provide covered recipients the opportunity to review the data prior to submission to CMS, but doing so is not mandatory. We understand that the processes and systems of applicable manufacturers and applicable GPOs may not allow for a review of this capacity. Similarly, since there is a post-submission review period, we do not believe that it is worth the additional burden for applicable manufacturers and applicable GPOs to make significant system changes in order to provide a pre-submission review. However, we do believe a pre-submission review could be extremely useful and recommend that applicable manufacturers and applicable GPOs consider ways that they could administer a pre-submission review external to CMS. Because CMS is not requiring the review, we do not feel it is appropriate for CMS to prescribe the process and standardize it; nevertheless, we believe that ongoing notice throughout the year of any reportable interactions would be ideal.

2. Report Submission

Applicable manufacturers and applicable GPOs are statutorily required to submit their reports for the preceding calendar year electronically to CMS on March 31, 2013 and on the 90th day of each calendar year thereafter. We proposed to interpret ''on'' March 31, 2013 or the 90th of the each year thereafter as ''by'' March 31, 2013 or the 90th of each year thereafter and intend to allow applicable manufacturers and applicable GPOs to submit data prior to this date to provide applicable manufacturers and applicable GPOs with more flexibility for submission. We did not receive any comments on this interpretation and have finalized it as proposed; however, as discussed in the timing section, because of the publication date of this final rule, reports including 2013 data will not be due until March 31, 2014.

a. Registration

In the proposed rule, we proposed that only applicable manufacturers that have payments or other transfers of value and/or physician ownership or investment interests to disclose for the previous calendar year must register and submit reports. Similarly, we proposed that only applicable GPOs with physician owners or investors would be required to register and submit information. For applicable manufacturers and applicable GPOs that did have information to disclose, we proposed that applicable manufacturers and applicable GPOs register with us prior to submission to facilitate communication. We proposed the registration process would require the applicable manufacturer or applicable GPO to designate a point of contact, which we would use for communications related to the submitted data. Alternatively, we considered requiring that all applicable manufacturers and applicable GPOs register with CMS, regardless of whether they had information to report, in order help us better understand the extent of these relationships and ensure compliance with the reporting requirements.

Comment: Many commenters supported the registration requirement, but disagreed on which entities should be required to register. Some commenters supported the proposal to require registration only by those entities with payments or other transfers of value or ownership or investment interests to report; other commenters recommended that CMS employ the alternative and require all entities that meet the definition of applicable manufacturer or applicable GPOs to register.

Response: Given the comments received, we believe that we do not need to require all entities that meet the definition of applicable manufacturer or applicable GPO to register and have finalized the position as proposed. Because the statute only requires the reporting of payments or other transfers of value, we will not require action by entities without payments or other transfers of value to report. All applicable manufacturers with payments or other transfers of value to report under paragraph 1 of the definition must register individually, regardless of whether they intend to be part of a consolidated report being submitted by another applicable manufacturer. We believe this will better allow CMS to ensure that applicable manufacturers required to report are reporting under the reporting requirements. However, applicable manufacturers that are submitting data as a part of a consolidated report under another applicable manufacturer may indicate during registration that they intend to be part of the consolidated report to be submitted by another

applicable manufacturer, allowing CMS to approximate the number of consolidated reports to anticipate. Additionally, as stated in the applicable manufacturer section, the reporting entity submitting a consolidated report must indicate all the applicable manufacturers for which it is reporting. Similarly, applicable manufacturers that are reporting separately must each register individually.

Comment: A few commenters discussed reporting of the point of contact, specifically recommending that two points of contact be provided for a single applicable manufacturer or applicable GPO.

Response: We agree that establishing and maintaining appropriate points of contact are important because it is essential that we be able to contact applicable manufacturers and applicable GPOs in the event that questions arise regarding their submission. We believe that requiring a second point of contact to serve as a backup will be beneficial and ensure that CMS can contact applicable manufacturers and applicable GPOs. We are finalizing that applicable manufacturers and applicable GPOs must indicate two points of contact when they register to allow for a primary and backup point of contact for each reporting entity. In order to ensure that the points of contact are up to date in the CMS system, applicable manufacturers and applicable GPOs will be able to change them as appropriate (subject to CMS user security protocols).

We did not receive any comments on our proposed timing for registration, so we have finalized those provisions as proposed. We proposed that applicable manufacturers or applicable GPOs with payments or other transfers of value to report must register prior to the deadline for data submission for data for the preceding calendar year for every annual reporting cycle. We intend applicable manufacturers and applicable GPOs to register sufficiently prior to the deadline in order to allow registration to be completed appropriately. Applicable manufacturers or applicable GPOs will be able to choose to submit the data immediately after completing the registration process successfully. We proposed to open the registration process at the beginning of the calendar year, giving applicable manufacturers and applicable GPOs time to register and submit their data; however, we may open registration earlier to allow additional time.

b. File Format

We also received several comments of the format of the data and process for submission to CMS. We proposed that applicable manufacturers and applicable GPOs submit their data electronically in a comma-separated value (CSV) format and solicited comments on and suggestions for alternatives to that format. Additionally, we proposed that each line item in the dataset should represent a unique payment or other transfer of value, or a unique ownership or investment interest. In the event that a single file does not have sufficient volume for all the data required, then we proposed the applicable manufacturer or applicable GPO could submit as many files as necessary to provide the entirety of its data.

Comment: Many commenters recommended that CMS create a standardized format and template and allow stakeholders an opportunity to review. Additionally, a few commenters supported the use of CSV files, whereas a few other commenters recommended using Pipe Line Delineated files rather than CSV files. These commenters explained that since some numbers are presented with comma separators (for example, $100,000), CSV files may be problematic. Similarly, a few commenters recommended that CMS establish a uniform naming system for applicable manufacturers.

Besides the format of the report, we also received comments on the organization and submission of the data. A few commenters recommended that CMS accept submission of data multiple times throughout the year, such as quarterly or ongoing, and allow extensions. Conversely, other commenters recommended allowing applicable manufacturers to submit multiple reports, organized by topic or individual. Finally to receive the data, a few commenters recommended that CMS develop a data exchange and data portal to accept files.

Response: We appreciate the comments and agree that CMS should provide applicable manufacturers and applicable GPOs with reporting templates and more details on reporting. However, we do not believe it is necessary or beneficial to provide this information in regulation, in order to allow the agency more flexibility to make changes in response to feedback from stakeholders. If we intend to make changes to the reporting template or other details for reporting (which we envision could happen particularly as the program evolves in early years), we will provide them at least 90 days prior to first day of data collection for the next reporting year. In providing revised templates, we will also comply with the requirements of the Paperwork Reduction Act to seek public comments on the proposed changes to the information collections, as required by law. This will allow applicable manufacturers and applicable GPOs to make any necessary changes to prepare for the next reporting year. This is the same time as the date by which we will publish the list of teaching hospitals.

We appreciate the comments on the organization of the submitted files, but per the statute, we will only allow submission of a single report consisting of the entire reporting period (for example CY 2014). We will only be collecting and staging data for public posting in accordance with annual submissions, so we will not be accepting ongoing or quarterly submissions. We believe that not only is annual publication sufficient for end users, but also allows for a single review and dispute period prior to publicly publishing the data, which is operationally easier for all parties. In addition, submission extensions will not be granted. After receiving all the submitted data, we will need to process all the data to aggregate across manufacturers and applicable GPOs and provide a single review and dispute period to correct submitted data prior to public posting. Late data will be considered failure to report and may be subject to penalties. Similarly, as required in the regulations, applicable manufacturers and applicable GPOs should not aggregate any payments or other transfers of value, or ownership or investment interests (except as described for small payments or other transfers of value). All reported transactions must be at the individual payment or other transfer of value, or ownership or investment interest level and do not intend applicable manufacturers or applicable GPOs to organize or group specific transactions. Finally, we appreciate the comments regarding a data exchange portal and agree that CMS should create an electronic system for accepting the data. We plan to publish additional information along with greater detail on the submission process.

c. Attestation Process

In the proposed rule, we proposed that annually, following the submission of data, an authorized representative from each applicable manufacturer and applicable GPO will be required to submit a signed attestation certifying the timeliness, accuracy, and completeness of the data submitted to the best of the

signer's knowledge and belief. We specified that such attestations must be signed by the chief executive officer, chief financial officer or chief compliance officer.

Comment: The majority of commenters supported the attestation requirement. However, a few commenters recommended revising the attestation to certify that the entity made a reasonable effort to ensure that data meets regulatory requirements. These commenters explained that the reporting requirements are, in their view, complicated, so it would be impossible to know whether the data submitted was accurate. Similarly, a few commenters suggested that CMS allow other officers (at the discretion of the reporting entity) to attest.

Response: We appreciate the comments, but we continue to believe that applicable manufacturers and applicable GPOs can and should be confident that the data is accurate. We recognize that the reporting requirements require significant data to be collected, but the majority of comments supported the language without revision, suggesting that reporting entities can be confident in their data. Additionally, the penalties are significantly less for unknowing errors, so the statute provides safeguards for unexpected errors. Finally, we do understand that applicable manufacturers and applicable GPOs may have different business structures. We do not want to confine applicable manufacturers and applicable GPOs with regard to which officers must attest, so we have finalized that other officers will be allowed to attest, as designated by the company.

We also seek to clarify the timing of the attestation requirement. Applicable manufacturers and applicable GPOs must provide an attestation for their data at the time of original submission for it to be considered submitted; however, they will also be required to provide an attestation any time the data is changed or updated. The most recent data for which there is an attestation will be considered the official data submission from the applicable manufacturer or applicable GPO. Data without such attestation will not be considered an official submission for purposes of reporting under section 1128G of the Act. This is discussed in more detail in the section on dispute resolution. However, we believe this may alleviate some of the concerns of applicable manufacturers regarding the difficulty in knowing whether the data submitted originally will be appropriately amended during the review and correction period.

Finally, as discussed in the section on applicable manufacturers, applicable manufacturers for which covered drugs, devices, biologicals, or medical supplies represent less than 10 percent of total (gross) revenue for the preceding year that have payments or other transfers of value to report, as a part of the attestation process, must attest that less than ten percent of total (gross) revenue in the immediately preceding year came from covered drugs, devices, biological, or medical supplies. We also note that for consolidated reports, the applicable manufacturer that submitted the consolidated report will be required to attest on behalf of all the entities included in the consolidated report. Applicable manufacturers that have reportable payments or other transfers of value that are submitted through a consolidated report by another applicable manufacturer will be required to register with CMS, but will not be required to attest. Accordingly we encourage applicable manufacturers considering submitting a consolidated report to fully consider the ramifications of doing so, particularly the applicable manufacturer actually attesting on behalf of all the entities included in the consolidated report.

3. Report Content

We have outlined the fields of information to be included when reporting payments or other transfers of value and physician ownership and investment interests. Some changes have been made below based on comments submitted; however, these decisions and changes are discussed throughout the final rule. The asterisks indicate the additional information that we will require under the discretion provided by the statute.

For each payment and other transfer of value, the following information is required:

- Applicable manufacturer's name.
- Covered recipient's—

++ Name (for physicians only, provide name as listed in NPPES, including first and last name, and middle initial and suffix (if applicable));

++ Specialty (for physicians only);

++ Primary business street address (practice location);

++ NPI (for physicians only, as listed in NPPES);

++ State professional license number(s) for at least one State where the physician maintains a license, including the applicable State where the license(s) is held; *

- Amount of payment or other transfer of value in U.S. dollars.
- Date of payment or other transfer of value.
- Form of payment or other transfer of value.
- Nature of payment or other transfer of value.
- Name(s) of the related covered drug, device, biological, or medical supply, as applicable.
- NDCs of related covered drugs and biologicals, if any. *
- Name of entity that received the payment or other transfer of value, if not provided to the covered recipient directly. *
- Whether the payment or other transfer of value was provided to a physician holding ownership or investment interests in the applicable manufacturer. (Yes or No response).
- Statement providing additional context for the payment or other transfer of value (optional). *

For each research-related payment or other transfer of value, the following information is required:

- Applicable manufacturer's name.
- Name of research institution/entity receiving payment.
- Total amount of research payment.
- Name of study.
- Name(s) of related covered drug, device, biological or medical supply (same requirements as for all payments or other transfers of value).
- NDCs of related covered drugs and biologicals, if any. *
- Principal investigator(s) (including name (as listed in NPPES), NPI (as listed in NPPES), State professional license number(s) for at least one State where the physician maintains a license including the applicable State where the license(s) is held, specialty and primary business address).
- Context of research (optional).
- ClinicalTrials.gov identifier (optional).
- Whether the payment or other transfer of value should be granted a delay in publication because it was made pursuant to a product research agreement, development agreement, or clinical investigation. (Yes or No response).

For each physician ownership or investment interest, the following information is required:

- Applicable manufacturer's or applicable GPO's name.
- Physician owner or investor's—

++ Name (as listed in NPPES, including first and last name, middle initial, and suffix (if applicable));

++ Specialty;

++ Primary business street address (practice location);

++ NPI (as listed in NPPES);

++ State professional license number for at least one State where the physician maintains a license including

the applicable State where the license(s) is held; * and

• Whether the ownership or investment interest is held by the physician, or an immediate family member of the physician.

• Dollar amount invested.

• Value and terms of each ownership or investment interest.

• Any payments or other transfers of value provided to the physician owner or investor, including the following (applicable manufacturers should report this information with their other payments or other transfers of value, and indicate that the covered recipient is a physician investor or owner):

++ Amount of payment or other transfer of value in U.S. dollars.

++ Date of payment or other transfer of value.

++ Form of payment or other transfer of value.

++ Nature of payment or other transfer of value.

++ Name(s) of related covered drugs, devices, biologicals, or medical supplies.

++ NDCs of related covered drugs and biologicals, if any. *

++ Name of entity that received the payment or other transfer of value, if not provided to the physician owner or investor directly. *

++ Statement providing additional context for the payment or other transfer of value (optional).*

4. 45-Day Review Period for Applicable Manufacturers, Applicable GPOs, Covered Recipients, and Physician Owners or Investors

Section 1128G(c)(1)(C)(ix) of the Act requires that the Secretary allow applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors the opportunity to review the data submitted for a period of at least 45-days prior to the data being made available to the public. This section outlines the comments received on the processes for and length of this review and correction period.

a. Notification of Review and Correction Period

In the proposed rule, we stated that we would notify covered recipients and physician owners or investors about the review and correction period in a few ways. We proposed to allow, but not require, covered recipients, and physician owners or investors to register with CMS to ensure they receive communication about the processes for review. Additionally, we proposed to notify physicians and hospitals through CMS's list-serves and by posting the information publicly (for example: on the CMS Web site or in the **Federal Register**). We also considered an alternative method, in which we would require applicable manufacturers and applicable GPOs to collect and report whether the covered recipient, or physician owner or investor would like to be notified by USPS or email of the processes for their review, as well as the individual's email address, if indicated. We received numerous comments on this which are described later in this section.

Finally, we proposed that the notification to physicians and teaching hospitals would be provided annually to announce the review and correction period, and would include the specific instructions for performing this review. We did not receive any comments on this provision, so we have decided to finalize it as proposed.

Comment: Many commenters addressed how to notify physicians and teaching hospitals of the opportunity to review payments or other transfers of value or ownership or investment interests that were attributed to them in reports submitted by applicable manufacturers or applicable GPOs. Some of these commenters supported the methods outlined in the proposed rule and provided other suggestions. Many commenters requested that physicians and teaching hospitals be notified personally of the processes for review and correction. Some of these commenters recommended the alternative method of collecting contact information (applicable manufacturers and applicable GPOs providing preferred method of communication), while others recommended another method or simply stated that CMS should notify physicians and teaching hospitals, but supported flexibility in the notification method. Conversely, many other commenters indicated that the proposed alternative would be overly burdensome, and recommended that CMS notify physicians and teaching hospitals in another manner. Finally, some commenters recommended more ongoing approaches to notification and allowing review to happen multiple times throughout the year.

Response: We appreciate the comments and have tried to balance the necessity to notify physicians and teaching hospitals with the desire to avoid adding any additional burden on applicable manufacturers and applicable GPOs. We have also considered what is operationally possible and concluded that we will notify physicians and teaching hospitals, as proposed, using email list serves, online postings (including both on the CMS Web site and the **Federal Register**) and directly (likely by email) to any physicians or teaching hospitals that have registered with CMS ahead of time. We strongly recommend that all covered recipients and physician owners or investors register. Although registration is not mandatory for these entities, in order for covered recipients to be able to review the data attributed to them, they will be required to register so we can appropriately match them to their data. In addition to the methods proposed, we plan to work with physician professional societies and provide the information to applicable manufacturers and applicable GPOs to provide voluntarily to covered recipients and physician owners or investors. We understand that these methods do not constitute direct, personal notification, but believe that these methods are sufficient and significantly more cost effective for both CMS, and applicable manufacturers and applicable GPOs.

Finally, we note that since applicable manufacturers and applicable GPOs only submit data for the previous calendar year to CMS once annually, the agency may not provide ongoing notifications to covered recipients or physician owners or investors for data submitted on their behalf outside of the formal period (such as in response to a dispute). Similarly, we will only provide for one formal review and correction period prior to the publication of that year's data. We discuss our plans to allow for updates to submitted data or submission of data previously omitted, as well as additional time to review and dispute, later in this section, but the formal review and correction period will only happen once annually prior to the next publication on the public Web site.

b. Length of Review and Correction Period

Section 1128G(c)(1)(D) of the Act requires that CMS provide a review and correction period of ''not less than 45 days.'' We proposed a 45-day review period to maximize the time for the agency to aggregate and publish the data. Additionally to facilitate the review, we proposed that applicable manufacturers, applicable GPOs, covered recipients, and physician owners and investors would sign into a secure Web site to view the data submitted. We proposed that only the current and previous years would be available for review and correction. For example, during the 45-day review period in 2015, applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors would be able to

review and amend the data submitted for 2013 and 2014. During the 2016 review, 2014 and 2015 would be available for changes.

Comment: Many commenters requested a longer review period, particularly to allow for additional time to resolve disputes. Many of these commenters recommended a 60- or 90-day review period and asked that the review period include a distinct phase to resolve disputes. These commenters stated that this was particularly important for disputes which may be initiated towards the end of the review and correction period.

Response: We appreciate the comments and are sympathetic to the need to provide time for review and correction and tried to maximize the time as much as possible. However, time constraints restrict flexibility in this area given the statutory date for publication of the submitted data on the public Web site. In finalizing the proposal, we tried to balance providing appropriate time for review which allows us sufficient time to process the data for review and publication. Following the first year of reporting, in which we must publish the data within approximately 6 months of receiving the data, we must thereafter publish the data within 90 days of the last day for data submission (March 31), so a 90-day review period is not feasible. Similarly, we also believe that a 60-day review period would not leave us enough time to aggregate the data and prepare it for publication within 90 days of data submission. Nevertheless, we do agree that there should be a distinct phase for correcting data to resolve disputes since we recognize that it is not practical to resolve disputes initiated at the end of the review and correction period, within the time allotted. We believe that there should be a distinct period after the review and correction period specifically for correcting data to resolve potential disputes.

Given these constraints, we have finalized a 45-day review and correction period, during which covered recipients and physician owners and investors may register and then sign into the CMS secure Web site and review the data submitted by applicable manufacturers and applicable GPOs on their behalf and choose to dispute certain payments or other transfers of value, or ownership of investment interests. As soon as a dispute is initiated, applicable manufacturers or applicable GPOs may begin resolving the dispute and correcting the data. Following the end of the review and correction period, applicable manufacturers and applicable GPOs will have an additional 15 days to correct data for purposes of resolving disputes, and after which they may submit (and provide attestation for) updated data to CMS to finalize their data submission. Undisputed data will be finalized for publication after the close of the annual 45-day review and correction period. Regarding the 15-day period for resolving and correcting disputes following the 45-day review period, we recognize that 15 days is not much time for applicable manufacturers and applicable GPOs to resolve disputes submitted late in the review and correction period. Because we do not believe that we have the authority to shorten the period when covered recipients and physician owners and investors can review and submit corrections to the data, the 15-day period to correct data and resolve disputes must be after the 45-day review and correction period. Extending the 15-day dispute resolution period would not allow us sufficient time to prepare for public posting and we cannot delay public posting for the review and correction period. Only data changes initiated during the 45-day review and correction period and resolved by the end of the 15-day period for dispute resolution will be captured in the initial publication of the current reporting year of data on the public Web site. Disputes submitted earlier in the review and correction period will have more time to be resolved. In order to try to maximize the successful resolution of disputes and have more accurate data for publication, we plan to encourage covered recipients and physician owners and investors to register with the CMS system, review their data and if necessary, initiate disputes as soon as possible within the 45-day review and correction period to maximize the likelihood of successful resolution and accurate data available for publication.

We also note that covered recipients and physicians owners and investors will have the opportunity to review and submit corrections for data updated by applicable manufacturers and applicable GPOs (either in response to a dispute, omission, or other error). There is no limit to the number of times a particular transaction can be reviewed and disputed.

Comment: Many commenters also discussed the processes for the review and correction period, including what data would be available during the 45-day period. The majority of these commenters supported the secure Web site to view the data and recommended that CMS determine a process to validate the identities of the applicable manufacturers. Regarding the data available, many commenters recommended that CMS allow review and correction of more data, beyond the 2 previous years. Additionally, a few commenters recommended that for data granted delayed publication, CMS should allow review and correction of the data in the year the data is submitted, rather than the year it will be published. These commenters explained that it will be easier for covered recipients and physician owners and investors to review and correct the data immediately after the payment was made, rather than up to four years later.

Response: We appreciate the comments on the review and correction process and what data should be available for review during the review and correction period. Regarding the review and correction process, we have finalized our proposal of facilitating the process on a CMS-secure Web site. We are working to develop a system to allow secure registration, data submission, data review and submission of corrections processes. Applicable manufacturers and applicable GPOs will only be able to access and review the data they submitted or that was submitted for them within a consolidated report submitted by another covered entity; covered recipients and physician owners and investors will only be granted access to data regarding payments or other transfers of value and/or ownership or investment interests submitted on their behalf. We agree that we will need to validate the identities of individuals signing on to the Web site and plan to employ a system that will allow for secure user identification and authorization. We also plan to allow physicians and teaching hospitals to register prior to the start of the annual formal review and correction period to establish their profile, allowing them immediate access to the information at the beginning of the formal review and correction period. The secure user-based authentication requires that the actual individual register and interact with the system to ensure the utmost security of the data. The registration process will also help us collect additional information from the covered recipients and physician owners or investors to ensure that only the appropriate data is available to them and able to be aggregated and presented to the appropriate individual.

Beyond the process for accessing the information, we do not agree that more than 2 years of data should be available for review and correction. While we believe that covered recipients and physician owners and investors should have appropriate opportunity to review the data, we believe that the data should

be finalized and no longer open to disputes and updates after a certain time period. As discussed later in this section, we have worked to improve the review and correction processes to allow covered recipients and physician owners and investors the opportunity to review and correct their data and resolve disputes with applicable manufacturers and applicable GPOs throughout the year. Given this increased flexibility, we believe that allowing only the review of the previous year's data (submitted in that year) provides covered recipients and physician owners and investors sufficient time to review and, if necessary, correct disputes.

Additionally, we agree that all data from the previous reporting year, including data granted delayed publication should be available for review during the review and correction period following the reporting year. For example, a payment or transfer of value granted delayed publication, but made in 2014 and reported in 2015, would be made available to the covered recipient for review and correction in 2015, but would not be published until the appropriate time for release. We believe covered recipients and physician owners and investors, as well as applicable manufacturers and applicable GPOs will be better able to review and correct the data during the period of time immediately following the transaction, rather than years afterward when the data is about to be published. Finally, we intend to provide additional information and guidance on the reporting requirements and timing of data review and correction to help applicable manufacturers, applicable GPOs, covered recipients and physician owners or investors understand how transactions should be reported.

c. Dispute Resolution

In the proposed rule, we provided information on the public presentation of disputed, but unresolved transactions. We proposed that if an applicable manufacturer or applicable GPO, and covered recipient, or physician owner or investor have contradictory information that cannot be resolved by the parties involved, then the data would be identified as contradictory and both the original submission from the applicable manufacturer or applicable GPO, and the modified information provided by the covered recipient or physician owner or investor, would appear in the final publicly available Web site. We also proposed that for aggregation purposes, we would use the contradictory data, as corrected by the covered recipient or physician owner or investor, for any aggregated totals.

We also received numerous comments on the proposed process for dispute resolution. In the proposed rule, we stated that we should not be actively involved in arbitrating disputes between applicable manufacturers or applicable GPOs, and covered recipients, or physician owners or investors regarding the receipt, classification or amount of any payment or other transfer of value, or ownership or investment interest. We proposed that covered recipients, and physician owners or investors may request from us the contact information for a specific applicable manufacturer or applicable GPO, in the event of a potential dispute over the reported data. However, it would be the responsibility of the covered recipient, or physician owner or investor, to contact and resolve the dispute with the applicable manufacturer or applicable GPO. We proposed that at least one of any entity involved (applicable manufacturer, applicable GPO, covered recipient, or physician owner or investor) must report to CMS that a payment or other transfer of value, or ownership or investment interest is disputed and the results of that dispute.

Regarding the timing for submitting disputes, we proposed that the 45-day review period is the primary opportunity to correct errors or contest the data submitted by applicable manufacturers and applicable GPOs to CMS. Once the 45-day review period has passed and the parties have identified all changes or disputes and we have made or noted them all, we proposed that neither applicable manufacturers, applicable GPOs, covered recipients, nor physician owners or investors would be permitted to amend the data for that calendar year. We also proposed that applicable manufacturers, applicable GPOs, covered recipients, or physician owners or investors alert us as soon as possible regarding any errors or omissions, but these changes may not be made until the data is updated for the following reporting year. At that time, all parties would once again have an opportunity to review and amend the data. However, we proposed that we would have the option to make changes to the data at any time (for example, to correct mathematical mistakes).

Comment: Commenters had mixed reactions to the proposal that CMS not play a central role in mediating disputes. Many commenters stated that CMS should manage the process to ensure it is standardized and intervene in situations when disputes cannot be resolved. Conversely, many other commenters supported that CMS should not be involved and that it should be at the discretion of the disputing parties. Many commenters also recommended options for resolution, such as engaging a third party to mediate the disputes or developing an appeals process.

Several commenters recommended that CMS allow applicable manufacturers and applicable GPOs discretion over which payments or other transfers of value or ownership or investment interests to resolve. A few of these commenters noted that the statute only requires that CMS grant a review and correction period, but not that all disputes must be resolved. Conversely, a few commenters recommended that CMS impose a materiality threshold, and applicable manufacturers and applicable GPOs would not be required to resolve disputes below the threshold. Additionally, a few commenters recommended that applicable manufacturers and applicable GPOs should be responsible for reporting the resolution of disputes to CMS since they are subject to penalties for incorrect reporting. Most of these commenters recommended that applicable manufacturers and applicable GPOs should be allowed to re-certify the data after the dispute resolution. Finally, a few commenters discussed how the post-submission review process would interact with a pre-submission review.

Response: We appreciate the comments and agree that effective and accurate resolution of disputes is essential to the program. After reviewing the comments, we believe that we do have a responsibility to facilitate the capability for correcting the data and resolving disputes among the parties. However, we maintain that we should not be actively engaged in mediating dispute resolutions. The relationship exists between the applicable manufacturer or applicable GPO, and the covered recipient or physician owner or investor, so these parties should be involved in the resolution of the dispute, not CMS. We believe that we are not the appropriate party to mediate the disputes. However, we do plan to provide the opportunity for covered recipients, or physician owners or inventors to review and correct the data submitted on their behalf. We also plan to monitor the rate of disputes and resolutions, including whether an applicable manufacturer or applicable GPO has an abnormally high number of disputes or has an abnormally high rate of unresolved disputes.

When covered recipients and physician owners or investors register and sign on to the secure CMS Web site,

all payments or other transfers of value, and all ownership or investment interests, submitted on their behalf will be available for review. The covered recipient or physician owner or investor will be responsible for reviewing each payment or other transfer of value, or ownership or investment interest, and will be able to initiate a dispute on a particular transaction, if he/she chooses. If a covered recipient or physician owner or investor decides to initiate a dispute, he or she will be directed to fill out electronic fields detailing the dispute, including the proposed corrections. The system will automatically flag that the transaction was disputed and the system will notify the appropriate applicable manufacturer or applicable GPO of the dispute, detailing the information submitted by the disputing covered recipient or physician owner or investor. The applicable manufacturer or applicable GPO and physician or teaching hospital will then be responsible for resolving the dispute, after which the applicable manufacturer or applicable GPO will be responsible for submitting corrected data and re-attesting to the new data by the end of the 15-day resolution period. If a dispute cannot be resolved in this time, the parties may and should continue to work to reach resolution and update the data. However, we will continue to move forward with publishing the original and attested data, but will mark it as disputed.

If an applicable manufacturer or applicable GPO submits updated data to resolve dispute(s), the applicable manufacturer or applicable GPO must re-attest to the timeliness, accuracy, and completeness of the data, as required during the original data submission. If an applicable manufacturer or applicable GPO does not update its data at the end of the correction period, then its original attestation will be used. We recognize that this requirement adds a second attestation for applicable manufacturers and applicable GPOs that submit updated data, but we believe it is important that all the data presented on the public Web site be subject to the same attestation requirements. We also believe applicable manufacturers and applicable GPOs will appreciate the opportunity to re-attest in response to any updates to the data changed during the review and correction period.

Additionally, we do not agree that the statute does not require applicable manufacturers and applicable GPOs to resolve disputes. We believe that by requiring a review and correction period, Congress intended any disputes identified to be resolved; however, we do recognize that there may be situations when the cost of initiating and resolving a dispute may not be worth the potential benefits. We intend to monitor the volume and terms of disputes and resolutions, and plan to provide additional guidance regarding situations when the cost of resolving a dispute may outweigh the benefits. Finally, since we are neither requiring, nor managing the pre-submission review process, we do not believe there should be any connection between any pre-submission processes and the CMS processes for data submission and review and correction. For example, we will not restrict a physician who reviewed and approved a payment in the pre-submission review from disputing such payment or other transfer of value during the CMS process for review and correction, since we will not know whether the physician received an opportunity to pre-review the payments or the result of his/her pre-review.

Comment: Numerous commenters opposed CMS's proposed approach for presenting disputed data. Many commenters stated that it would be misleading to end users of the data to include both accounts. However, they differed in their preferred options for presenting unresolved transactions. Several commenters recommended that disputed transactions should be flagged as disputed, but only one account of the transaction be included. The majority of these commenters suggested that the information, as submitted by the applicable manufacturer or applicable GPO, should be the account of the transaction published, since they are the entities with the reporting requirements and subject to penalties. Other commenters recommended that the unresolved data should not be published until it has been resolved. Beyond the data reported, a few commenters recommended that CMS outline incentives for resolving disputes in order to ensure that applicable manufacturers, applicable GPOs, covered recipients and physician owners and investors participate in the dispute resolution process.

Response: We appreciate the comments and agree that publishing both accounts of a disputed transaction would be misleading. Although we believe publishing both accounts would provide the details of the dispute thereby providing the greatest transparency, we believe that this level of detail would not be useful for end users of the data. We also agree that any disputed transactions that have not yet been resolved should be labeled as such, but that only a single account of the transaction should be listed on the public Web site.

We also do not agree that disputed transactions should not be published publicly until they are resolved. We believe that this method would potentially create an incentive for covered recipients and physician owners or investors to dispute each transaction of the public Web site to prevent them from being made public. We also believe that publication of disputed transactions will incentivize the parties to resolve disputes in a timely manner. We do not believe that any additional incentives are necessary. We believe that the interest to only publish accurate and undisputed information will push all parties to actively resolve disputes.

Therefore, we will finalize that on the public Web site, payments or other transfers of value or ownership or investment interests that cannot be resolved by the end of the 15-day resolution period will be marked as ''disputed,'' but the applicable manufacturer's or applicable GPO's most recent attested data subject to the dispute will be the only account of the information published. We believe publishing the most recent attested account by the applicable manufacturer or applicable GPO (rather than the corrected account provided by the covered recipient or physician owner or investor during the review and correction period) is appropriate because applicable manufacturers and applicable GPOs are responsible for collecting, reporting, and attesting to the accuracy of the information and are subject to penalties for failure to report. The parties may continue to resolve disputes after the close of the resolution period and after the data has been published publicly, or may leave the data as disputed; however, we discouraged leaving data as disputed and advocate for timely dispute resolution.

Comment: Several commenters did not support the 45-day review period being the only opportunity to review and correct the data and recommended that review and correction be available more frequently. Many commenters also recommended that CMS allow for changes to be made more than once annually to ensure that mistakes are identified and corrected on the public Web site as soon as possible. Finally, a few commenters also recommended that applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors should not have to report mistakes immediately, but allow time to investigate the mistake internally.

Response: We appreciate the comments on updating the public Web site and agree that we have a responsibility to allow for updates to the data more frequently than once a year during the formal 45-day review and correction period and 15-day resolution period, particularly given the short time period for the data to be reviewed and updated. We believe that some disputes will not be resolved in time for updated data to be included in the public data release for that reporting year, but will be resolved and require changes thereafter. These should not be incorrectly listed on the Web site for a whole year, when they have in fact been resolved. Nevertheless, we also believe that we do not have the resources to make continual changes to the Web site and should not be required to continually update the data. We will update the current and a previous year's data at least once annually, beyond the initial data publication following the submission of the data.

Similarly, we also believe that covered recipients, and physician owners or investors should be allowed to review and dispute the contents of the public Web site throughout the year. After registering with the CMS system, physicians and teaching hospitals, and physician owners and investors may sign in to the system to review or dispute officially submitted and attested transactions any time during the year. However, any disputes and subsequent updates initiated and resolved outside the 45-day review and correction period and 15-day resolution period may not be reflected on the public Web site until the next update of the data. We believe this fairly allows covered recipients and physician owners or investors control over reviewing and correcting their data at all times, but does not require us to make continual changes to the published data. This system will also allow covered recipients and physician owners and investors the opportunity to easily and efficiently review (and dispute, if necessary) data updated and re-submitted by an applicable manufacturer or applicable GPO.

Finally, we also understand applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors may want to investigate errors internally before notifying CMS of errors or omissions. However, we believe that errors and changes need to be reported to us as soon as possible so that we have the most accurate information possible. We believe that covered recipients and physician owners or investors should use the CMS review and correction processes to report errors and begin to resolve them with applicable manufacturers and applicable GPOs as quickly as possible. It will be the responsibility of the applicable manufacturer or applicable GPO that submitted and attested to the data to submit any updates, including errors and omissions, immediately after confirming that an update is needed or an error needs to be corrected; failure to do so may be considered incomplete reporting and may give rise to penalties.

D. Public Availability

Under the statute, we are required to publish on a publicly available Web site the data reported by applicable manufacturers and applicable GPOs for CY 2012 by September 30, 2013. For each year thereafter, we must publish the data for the preceding calendar year by June 30th. Given the timing of the final rule, no data will be collected for CY 2012, so the first data publication will be in 2014 for data collected in 2013.

In the proposed rule, we noted that section 4 of Executive Order 13563 calls upon agencies to consider approaches that ''maintain flexibility and freedom of choice for the public,'' including the ''provision of information to the public in a form that is clear and intelligible.'' We requested comment on how to structure this Web site for ultimate usability and proposed, as required by statute, that the Web site will include information on any enforcement activities taken under section 1128G of the Act for the previous year; background or other helpful information on relationships between the drug and device industry and physicians and teaching hospitals; and publication of information on payments or other transfers of value that were granted delayed reporting.

Comment: Numerous commenters provided feedback on the public Web site, particularly the development of the Web site. Many commenters called upon CMS to solicit stakeholder assistance in the development of the public Web site and that stakeholders should be given the opportunity to comment on the Web site content prior to it being finalized. A few commenters also recommended various methods to better develop the Web site, such as reviewing existing Web sites with similar information as examples. Finally, a few other commenters requested that CMS provide more information on the public Web site in the final rule.

Response: We appreciate the comments and agree that stakeholder input is essential to the success of the public Web site. We plan to engage stakeholders regarding the content of the Web site, since we recognize that stakeholders and the public must be a part of the development process. We agree that it is important that the final Web site is user-friendly and provide accurate and understandable information to the public. In order to regain flexibility over the details of the Web site and allow the opportunity to work with stakeholders on development, we have only provided general information on the public Web site in the final rule. We believe that it is important that we have flexibility to make changes to the Web site as they are identified, but do plan to engage the public on the future development. We intend to release additional information about the Web site through education and outreach to the stakeholder community.

Comment: In response to our request for comment on the structure of the public Web site, we received numerous comments recommending specific information to be included, as well as the Web site's capabilities. Some commenters recommended that specific information and research should be included on the Web site as background or contextual information, particularly including details of the reporting requirements and the benefits of relationships between manufacturers and physicians and teaching hospitals. Additionally, some other commenters recommended that CMS link to other Web sites, such as physician codes of conducts or a manufacturer's published data.

Regarding the capabilities of the Web site, some commenters recommended that the data should be easily searchable and downloadable. Other commenters recommended specific file structures and details for the data, for public use, as well as use by researchers, including allowing researchers to obtain information that is not publicly available.

Response: We appreciate the comments and agree that both the information included and capabilities of the Web site are extremely important. We support many of the recommendations and have provided general plans for the information to be presented, as well as the capabilities of the Web site. We plan to ensure that the public Web site accurately and completely describes the nature of relationships between physicians and teaching hospitals, and the industry, including an explanation of beneficial interactions. In addition, we plan to provide information to stakeholders regarding the data submission, review, dispute, dispute resolution and other

applicable operational processes. As proposed, the Web site will clearly state that disclosure of a payment or other transfer of value on the Web site does not indicate that the payment was legitimate nor does it necessarily indicate a conflict of interest or any wrongdoing. We appreciate the support of this language and plan to emphasize it on the Web site. We also plan to provide Frequently Asked Questions (FAQs) and other methods to help users find and understand this important contextual information.

While we appreciate that there is similar information available from industry and stakeholders that may be beneficial to include on the public Web site, we also want to try to reduce the promotional or company specific information on the Web site, so we will need to assess the best way to include this information, if at all. Finally, we are also cognizant that the Web site will include a significant amount of information and are considering the best way to provide sufficient context without overwhelming the consumer.

As required by statute, we plan to aggregate the data submitted and publish the data on a Web site that is searchable across multiple fields and available for downloads. In addition, we plan to establish mechanisms for researchers who may want information that is not publicly available. We believe that the data included in the database is primarily important for consumers, but understand that it also provides numerous opportunities for research on provider-industry relationships. We plan to provide opportunities to download the data that support researchers, as well as consumers, since we believe that research on this information is an important benefit of any transparency initiative.

1. Data Elements

In the proposed rule, we listed the data elements that would be available on the public Web site. We did not receive any comments on these, so we have finalized them as proposed. As required by statute, a physician's NPI will *not* be published on the public Web site. In these lists, we have included any necessary changes as required by other sections of the final rule. The asterisks indicate the additional information that we will publish under the discretion provided by the statute. As required in section 1128G(c)(1)(C)(ii) of the Act, at a minimum the following information on payments and other transfers of value would be included on the public Web site in a format that is searchable, downloadable, understandable, and able to be aggregated:

- Applicable manufacturer's name.
- Covered recipient's—
  - ++ Name;
  - ++ Specialty (physician only); and
  - ++ Primary business street address (practice location).
- Amount of payment or other transfer of value in U.S. dollars.
- Date of payment or other transfer of value.
- Form of payment or other transfer of value.
- Nature of payment or other transfer of value.
- Name(s) of the related covered drugs, devices, biologicals, or medical supplies, as applicable.
- NDCs of related covered drugs and biologicals, if any.*
- Name of the entity that received the payment or other transfer of value, if not provided to the covered recipient directly.
- Statement providing additional context for the payment or other transfer of value (optional).*

For research payments or other transfers of value, at a minimum the following research related information will be available on the public Web site:

- Name of research institution/entity receiving payment.
- Total amount of research payment.
- Name of study.
- Name(s) of the related covered drugs, devices, biologicals or medical supplies.
- NDCs of related covered drugs and biologicals, if any.*
- Principal investigator(s) (including name, specialty and primary business address).
- Context of research.
- ClinicalTrials.gov identifier (optional).

For physician ownership and investment interests, at a minimum the following information would be included on the public Web site in a format that is searchable, downloadable, understandable, and able to be aggregated:

- Applicable manufacturer's or applicable GPO's name.
- Physician owner or investor's—
  - ++ Name;
  - ++ Specialty; and
  - ++ Primary business street address.
- Whether the ownership or investment interest is held by the physician or an immediate family member of the physician.
- Dollar amount invested.
- Value and terms of each ownership or investment interest.
- Any payment or other transfer of value provided to the physician owner or investor, including:
  - ++ Amount of payment or other transfer of value in U.S. dollars.
  - ++ Date of payment or other transfer of value.
  - ++ Form of payment or other transfer of value.
  - ++ Nature of payment or other transfer of value.
  - ++ Name(s) of the related covered drugs, devices, biologicals, or medical supplies, as applicable.
  - ++ NDCs of related covered drugs and biologicals, if any.*
  - ++ Name of the entity that received the payment or other transfer of value, if not provided to the physician directly.
  - ++ Statement providing additional context for the payment or other transfer of value (optional).*

E. Delayed Publication for Payments Made Under Product Research or Development Agreements and Clinical Investigations

Section 1128G(c)(1)(E) of the Act provides for delayed publication of payments or other transfers of value from applicable manufacturers to covered recipients made pursuant to certain kinds of product research or development agreements and in connection with clinical investigations. This provision seeks to balance the need for confidentiality of proprietary information with the need for public transparency of payments to covered recipients that could affect prescribing habits or research outcomes.

In the proposed rule, we proposed that payments or other transfers of value would be granted delayed publication only if they were made in the context of a relationship for bona fide research or clinical investigation activities. We proposed that the ''product research or development agreement'' referenced in the statute included a written statement or contract between the applicable manufacturer and covered recipient, as well as a written research protocol.

Section 1128G(c)(1)(E) of the Act provides specific situations when delayed publication of payments or other transfers of value is appropriate, including the following:

- Research in connection with a potential new medical technology or a new application of an existing medical technology.
- The development of a new drug, device, biological, or medical supply.
- In connection with a clinical investigation regarding a new drug, device, biological, or medical supply.

In the proposed rule, we noted the difficulty in separating medical technology from the definition of covered drug, device, biological or medical supply and proposed to

consider ''medical technology'' broadly to include any drug, device, biological, or medical supply. Similarly, due to the overlap between the terms ''research'' and ''development,'' we proposed to treat them similarly in this provision. In the proposed rule, we noted that the definition of clinical investigations in section 1128G(e)(3) of the Act is distinct from both ''research'' and ''development'' for the purposes of section 1128G the Act. We noted that this definition may also differ from those that applicable manufacturers may be familiar with in 21 CFR 312.3 and 812.3.

Given these interpretations, we proposed that delayed publication should apply to payments to covered recipients for services in connection with research on, or development of, new drugs, devices, biologicals, or medical supplies, as well as new applications of existing drugs, devices, biologicals, or medical supplies. Conversely, we proposed limiting delayed publication for payments in connection with clinical investigations to *new* drugs, devices, biologicals, or medical supplies, but not new applications of existing drugs, devices, biologicals, or medical supplies.

Finally, the statute also requires that information about payments and other transfers of value that are delayed from publication must be made publicly available on the first publication date after the earlier of either: (1) the approval, licensure or clearance by the FDA of the covered drug, device, biological or medical supply; or (2) 4 calendar years after the date of payment or other transfer of value.

Comment: Numerous commenters provided input on these interpretations and proposals. Some commenters recommended that CMS expand the situations when a payment or other transfer of value may be granted delayed publication. For example, a few commenters suggested that all research-related payments or other transfers of value should be granted a delay in publication, regardless of the product under consideration. Some commenters also explained that research on non-covered products should also be granted delayed publication, including pre-clinical research, which is often not expressly connected to a product. Conversely, other commenters recommended that CMS narrow the situations when a payment or other transfer of value is granted delayed publication. For example, a few commenters suggested interpreting medical technology as a subset of covered drugs, devices, biologicals or medical supplies, which would include only devices or even only a subset of devices. A few commenters also recommended that CMS not allow any delayed publication for payments or other transfers of value related to new applications of existing products. Finally, a few other commenters requested that CMS allow for delayed publication of sensitive payments or other transfers of value that are not related to research, such as business development activities.

Response: We appreciate these comments. However, we believe that our proposal strikes a good balance for granting certain payments or other transfers of value a delay in publication. In order to provide additional context to stakeholders, we seek to clarify our interpretation of the proposed requirements for delayed publication.

All payments or other transfers of value that are related to research, as defined in § 403.902, and are made pursuant to a written research agreement for research related to *new* products will be granted a delay. However, payments or other transfers of value related to research for new applications of products already on the market will be treated differently due to the statutory distinction between new products and new applications of existing products. Pursuant to the statute, payments related to research on new applications of existing products will be granted a delay only if the research does not meet the definition of ''clinical investigation.'' We recognize that clinical investigations are a subset of research; however, we believe that the statute clearly differentiates them for purposes of delayed publication from research and development, and indicates that payments or other transfers of value made in connection with clinical investigations (as defined in section 1128G(e)(3) of the Act) related to new applications of existing products should not be granted a delay. Given the broad scope of the statutory definition of ''clinical investigation,'' we believe this includes Phases I through IV clinical research for drugs and biologicals, and approval trials for devices (including medical supplies). We also amended the regulatory definition to include biologicals and medical supplies, as well as drugs and devices, since all product types should be treated similarly.

We recognize that the interpretation of the meaning of a new product (as opposed to a new application of an existing product) for the purposes of section 1128G of the Act may differ from other definitions, such as the definition of new drug in 21 U.S.C. 355. For purposes of determining eligibility for delayed publication under section 1128G(c)(1)(E) of the Act, new generic products will be considered new products, including drugs receiving approval under an Abbreviated New Drug Application, and devices under the 510(k) process.

Finally, while we recognize the potentially sensitive nature of business development activities, we do not believe that the statute grants us the ability to granted delays for payment types other than research.

Regarding the written agreement and research protocol, we discussed numerous comments on these requirements earlier in the research section, particularly regarding the requirement that a research study must be subject to both a written agreement and a research protocol. We have finalized the same requirements for payments or other transfers of value granted delayed publication. In general, a payment or other transfer of value can only be granted delayed publication if the payment meets the definition of research and could be reported under the ''research'' nature of payment category. Any related payments or other transfers of value that would not be reported as a part of the research nature of payment category, pursuant to the discussion in section II.B.1.i. of this final rule, will not be granted delayed publication.

Comment: Commenters specifically recommended that 4 years is not enough time for full development of a product, and that payments should only be published after FDA approval, licensure or clearance.

Response: We appreciate the comments, but the timelines are clearly delineated in section 1128G(c)(1)(E) of the Act. We do not have the authority to alter them. Additionally, we believe Congress clearly intended that all payments should be included on the public Web site, even if a product never received FDA approval, licensure or clearance.

1. Process for Reporting Payments or Other Transfers of Value Granted Delayed Publication

We received numerous comments on our proposed method for notification to CMS which payments or other transfers of value are eligible for delayed publication on the public Web site, as well as additional methods for reporting the information to CMS. We proposed that applicable manufacturers should indicate on their reports whether or not a payment or other transfer of value should be granted a delay from publication. In addition, we proposed that payments or other transfers of value

subject to delayed reporting need to be reported each year with a continued indication that publication should remain delayed and any updated information on the payment or other transfer of value, as necessary. Further, we proposed that following FDA approval, licensure or clearance, applicable manufacturers must indicate in their next annual submission that the payment should no longer be granted a delay and should be published in the current reporting cycle. Finally, we proposed that if a report includes a date of payment 4 years prior to the current year, then the payment or other transfer of value would be automatically published, regardless of whether the applicable manufacturer indicates that the payment should be delayed.

Comment: A few commenters requested clarification on whether applicable manufacturers would be required to indicate that a payment or other transfer of value should be granted delayed publication. Other commenters provided alternative methods for reporting payments or other transfers of value eligible for delayed publication. For example, some commenters recommended that applicable manufacturers should only report the payment or other transfer of value to CMS in the year it was made and then again in the year it is to be published. Similarly, other commenters recommended that applicable manufacturers should only report payments or other transfers of value in the year they are to be published. In addition, a few commenters expressed concern about confidentiality and recommended that applicable manufacturers should not be required to report the identifying details of the payment or other transfer of value until the payment was scheduled to be published. Beyond identifying details, some commenters recommended that CMS allow applicable manufacturers to report ''research and development'' for the product name, rather than the product, in order to better protect proprietary interests. Similarly, commenters recommended that CMS never require the collection of research protocols in order to ensure a payment or other transfer of value should be granted delayed publication.

Response: We appreciate the comments and agree that applicable manufacturers are not *required* to indicate that payments or other transfers of value are eligible for delayed publication and may instead choose not to indicate eligibility for the delay. However, if a manufacturer does not indicate that a payment or other transfer of value is eligible for delayed publication, it will be published immediately on the next publication date.

We also appreciate the comments regarding alternative methods for reporting payments or other transfers of value granted delayed publication; however, we believe that the proposed method is preferable. We believe that continual reporting is beneficial because it will allow us to ensure that payments or other transfers of value made more than four years earlier will be published appropriately. Otherwise, payments or other transfers of value from the same applicable manufacturer may be stored in various places. Additionally, we believe it will be difficult for us to enforce and audit payments or other transfers of value eligible for delayed publication if they are not reported until they are scheduled to be published. Nevertheless, we understand the confidentiality concerns, particularly for new products that have not yet been granted FDA approval, licensure, or clearance. However, after reviewing the comments, we believe that allowing applicable manufacturers to report in a different manner and allowing special considerations for certain research payments or other transfers of value makes the reporting requirements significantly more complicated. Additionally, section 1128G(c)(1)(E)(ii) of the Act requires CMS to keep the information submitted confidential prior to publication. We believe that creating separate requirements is too burdensome particularly when the statute and regulations already provide for confidentiality. We do not intend applicable manufacturers to provide research protocols or other such agreements to CMS for verification. Finally, pursuant to the statute, information reported by applicable manufacturers that is subject to delayed publication under section 1128G(c)(1)(E) of the Act shall be considered confidential and shall not be subject to disclosure under 5 U.S.C. 552, or any other similar Federal, State or local law, until after the date on which the information is made available to the public via publication on the Web site.

F. Penalties

Section 1128G(b) of the Act authorizes the imposition of CMPs for failures to report required information on a timely basis in accordance with the regulations. If an applicable manufacturer or applicable GPO fails to submit the required information, then the applicable manufacturer or applicable GPO will be subject to a CMP of at least $1,000, but no more than $10,000, for each payment or other transfer of value, or ownership or investment interest not reported as required. The maximum total CMP with respect to each annual submission for failure to report is $150,000. For knowing failure to submit required information in a timely manner, an applicable manufacturer or applicable GPO will be subject to a CMP of at least $10,000, but no more than $100,000, for each payment or other transfer of value, or ownership or investment interest not reported as required. The maximum total CMP with respect to each annual submission for a knowing failure to report is $1,000,000.

In the proposed rule, we outlined the penalty amounts as required by statute for failure to report and knowing failure to report. In addition, we proposed that all CMPs would be collected and imposed in the same manner as the CMPs collected and imposed under section 1128A of the Act. Additionally, we proposed that the procedures in 42 CFR part 402 subpart A would apply with regard to imposition and appeal of CMPs. Similarly, we defined the term ''knowingly'' based on the meaning in the False Claims Act, 31 U.S.C. 3729(b), as required by statute. Finally, we also proposed that a CMP may be imposed for failure to report information in a timely, accurate, or complete manner.

In the proposed rule, we outlined the factors that we would consider when determining the amount of a CMP, as well as when the maximum CMP would be imposed. We did not receive any comments on these factors, so we have decided to finalize these provisions as proposed. The factors to be considered include, but are not limited to, the following:

- The length of time the applicable manufacturer or applicable GPO failed to report, including the length of time the applicable manufacturer and applicable GPO knew of the payment or other transfer of value, or ownership or investment interest.
- Amount of the payment or other transfer of value or the value of the ownership or investment interest the applicable manufacturer or applicable GPO failed to report.
- Level of culpability.
- Nature and amount of information reported in error.
- Degree of diligence exercised in correcting information reported in error.

Finally, we proposed that in order to facilitate audits and enforcement, applicable manufacturers and applicable GPOs must maintain all books, records, documents, and other materials sufficient to enable an audit, evaluation or inspection of the applicable manufacturer's or applicable

GPO's compliance with the requirements in section 1128G of the Act and the implementing regulations. We proposed that applicable manufacturers and applicable GPOs must maintain these books, records, documents, and other materials for a period of at least 5 years from the date the payment or other transfer of value, or ownership or investment interest is published publicly on the Web site.

Comment: A few commenters discussed the proposed penalties for failure to report. These commenters generally supported higher CMP amounts for knowing failures to report. However, a few of these commenters suggested that the penalties were too low. The commenters also recommended that penalties should be imposed for inaccurate reporting, as well as omitted transactions.

Beyond the structure of the penalties, a few commenters also requested additional information on how CMS planned to enforce the program. They requested information on which agencies would be responsible for enforcement, as well as the enforcement mechanisms. Finally, a few commenters requested clarification on when the maximum penalty would be imposed and recommended that errors corrected during the review and correction period would not be subject to penalties.

Response: We appreciate the comments. However, we cannot change the amount or terms of the penalties, since they were authorized by statute. Section 1128G(b) of the Act outlines the CMP amounts and requires that they are imposed and collected in the same manner as those in section 1128A of the Act. Nevertheless, we do agree that the penalties should be imposed for inaccurate reporting. We have finalized our proposal that a CMP may be imposed for failure to report information in a timely, accurate, or complete manner. This includes failure to report timely or accurately an entire transaction, as well as failure to report timely or accurately certain fields related to a transaction. For example, this could entail reporting an erroneous payment amount or not reporting that an ownership or investment interest was held by an immediate family member of a physician. In order to clarify this, we have revised the regulation text in 42 CFR 402.105 to include the same text regarding reporting in a timely, accurate, or complete manner. In addition, we have revised the regulation text at § 402.105 and § 403.912 to clarify that the penalties imposed for failures to report and knowing failures to report will be aggregated separately and are subject to separate aggregate totals, with a maximum combined annual total of $1,150,000. Finally, we also realized that in the proposed rule we did not refer to the procedures for collection of CMPs in 42 CFR part 402 subpart B, so we are clarifying in this final rule that the procedures in 42 CFR part 402 subpart A and subpart B will apply with regard to imposition, appeal, and collection of CMPs.

Regarding corrections made during the review and correction, and dispute resolution periods, we want applicable manufacturers and applicable GPOs to correct any errors they have submitted without fear of alerting CMS to errors that will be subject to penalties; however, we do not want to allow applicable manufacturers to submit grossly inaccurate or incomplete data by the original submission date without risk of sanction. Therefore, we are requiring applicable manufacturers and applicable GPOs to attest the timeliness, accuracy, and completeness of their original submission to CMS prior to the review and correction period. Applicable manufacturers and applicable GPOs should make a good faith effort to ensure that the original data submitted to CMS is correct. We do not intend that errors corrected during the review and correction, and dispute resolution periods will be subject to penalties for failure to report in instances when the original submission was made in good faith. As noted earlier, applicable manufacturers and applicable GPOs will be required to re-attest after the submission of updated or new data. Outside this period, any errors or omissions will be considered failures to report timely, accurately, or completely, and will be subject to penalties. Additionally, both CMS and the HHS OIG are authorized to impose CMPs and both agencies will have the ability to investigate failures to report timely, accurately or completely.

Finally, in light of the increased flexibility for consolidated reports, we have clarified how penalties will be enforced for applicable manufacturers submitting consolidated reports. As explained previously, for consolidated reports, the applicable manufacturer that submitted the consolidated report will be required to attest on behalf of all the entities included in the consolidated report. Therefore, the applicable manufacturer actually submitting the consolidated report and signing the attestation will be subject to the maximum penalties (based on unknowing and knowing failures to report) for each individual applicable manufacturer included in the consolidated report. For example, an applicable manufacturer submitted a consolidated report for itself (Company A) and two other applicable manufacturers (Subsidiary B and C). We discover six instances of a failure to report a payment or other transfer of value in Company A's submission (each penalized at $10,000), seven instances of a knowing failure to report in Subsidiary B's submission (each penalized at $100,000) and finally nine knowing instances of failure to report (each penalized at $100,000) in Subsidiary C's submission. Company A, as the submitter and attester of the data, would be subject to a penalty of $60,000 for Company A's failure to report, $700,000 for Subsidiary B and $900,000 for Subsidiary C. To be clear, Company A would be subject to the penalties for knowing failure to report from both Subsidiary B's and Subsidiary C's submissions even though the penalties together exceed $1,000,000, because we interpret the maximum to apply individually to each applicable manufacturer's submission, even if the submission is contained within a consolidated report. We believe this appropriately handles the penalty requirements for applicable manufacturers submitting consolidated reports, since each applicable manufacturer should be subject to the same maximum penalties regardless of whether it submits individually, or as a part of a consolidated report. Two applicable manufacturers submitting a consolidated report should not be subject to lower penalties than two applicable manufacturers not submitting a consolidated report. Additionally, because the applicable manufacturer submitting the consolidated report is the entity attesting to the data, we believe it is fair that it be subject to the CMPs for each applicable manufacturer included in the consolidated report. Therefore, as noted previously we encourage applicable manufacturers considering consolidated reports to fully assess the requirements and potential penalties.

Comment: A few commenters discussed the retention period; in particular, many of them stated that the 5-year retention period was too long. A few other commenters recommended that the 5 years should begin on the date of first submission, rather than the date of publication. These commenters explained that retention based on date of publication would require applicable manufacturers and applicable GPOs to retain some records for longer than 5 years. Finally, a few commenters questioned whether the 5-year retention requirement was considered absolute in terms of liability.

Response: We appreciate the comments, but do not agree that 5 years is too long. We believe that 5 years is sufficient, since it is less than other retention requirements with which applicable manufacturers and applicable GPOs may be familiar. In addition, we believe that the retention period should begin at the date of publication. While we understand this policy may require the records to be retained for up to 9 years, we believe this information is essential for audits, and given the confidentiality requirements for data granted delayed publication, these activities may not be possible until after the data is published. If the date of retention began when the data was reported, in some cases there may be less than a year between when the data was published and the end of the retention period, which we do not believe is sufficient time to allow for audits, penalties, and appeals. Given these decisions, we have finalized the retention requirements as proposed. Finally, the requirements set forth in this final rule are in addition to, and do not limit, any other applicable requirements that may obligate applicable manufacturers or applicable GPOs to retain and allow access to records.

G. Annual Reports

We are required to submit annual reports to the Congress and the States. The Report to Congress is due annually on April 1st, beginning April 1, 2013, and shall include aggregated information on each applicable manufacturer and applicable GPO submitted during the preceding calendar year, as well as any enforcement action taken and any penalties paid. Similarly, we must report information submitted during the previous year to States annually by September 30, 2013 and June 30 for each year thereafter. In the preamble to the proposed rule, we explained that since we will not receive data for the prior year until the 90th day of each year, the data submitted that year will not be ready for the April 1st report. Instead, we proposed that we report to the Congress information submitted by applicable manufacturers and applicable GPOs during the preceding year.

Finally, we proposed that the State reports would be State-specific and include summary information on the data submitted regarding covered recipients and physician owners or investors in that State. Since these reports are due later in the year than the Report to Congress, we proposed that the reports would include data collected during the previous calendar year which was submitted in the current year. We also proposed that neither the Congressional nor State reports will include any payments or other transfers of value that were not published under the delayed publication requirements in section 1128G(c)(1)(E) of the Act. We did not receive any comments on these provisions and have finalized them as proposed.

Comment: A few commenters did not support the proposed timing for the Congressional report and instead recommended that CMS publish the Congressional report along with the publication of the data. Additionally, a few commenters recommended that CMS provide more information on the content of the Congressional reports. Particularly, they recommended that the report provides aggregate spending across applicable manufacturers and applicable GPOs, including aggregate spending for payments or other transfers of value granted delayed publication. Finally, a few commenters also recommended that CMS establish a process for sharing information across government agencies, such as OIG and the Department of Justice (DOJ).

Response: We appreciate the comments. We agree that the annual Congressional report should include summary statistics on the annual aggregate totals across applicable manufacturers and applicable GPOs. We also agree that inclusion of the aggregate total of payments or other transfers of value would be useful for oversight of the program. We plan to include this information in our annual Congressional report; however, in general we believe that we should not include specific details in the final rule to allow us flexibility to include and present information as appropriate. We also plan to work closely with other Federal agencies, since we recognize that other agencies are involved in similar activities. However, the purpose of this program is not to prosecute reporting entities, but to promote transparency.

Regarding the timing of the Congressional report, we recognize the awkwardness of the timing, but note that the report could be submitted early since it is only required *by* April 1st. We do not believe we have the authority to change the statutory deadline in regulation, but will try to publish the report as soon as possible.

Based on the timing of the publication of the final rule we have finalized that the Report to Congress will be submitted annually on April 1st, beginning April 1, 2015, and will include aggregated information submitted by each applicable manufacturer and applicable GPO submitted during the preceding calendar year (that is, data collected in CY 2013 and submitted in March of 2014), as well as any enforcement actions taken and any penalties paid.

H. Relation to State Laws

Section 1128G(d)(3) of the Act preempts any State or local laws requiring reporting, in any format, of the same type of information concerning payments or other transfers of value made by applicable manufacturers to covered recipients. No State or local government may require the separate reporting of any information regarding a payment or other transfer of value that is required to be reported under section 1128G(a) of the Act, unless such information is being collected by a Federal, State or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight.

Comment: A few commenters discussed the relation of section 1128G of the Act to relevant State laws. These commenters strongly supported preemption, but requested information on how CMS interpreted the timing, given the missed statutory deadline. Many commenters also requested that CMS identify what elements of current State laws will be preempted. Additionally, these commenters recommended clarifying the statutory language to prevent preemption from being applied too narrowly to successfully consolidate reporting. A few commenters explained that a broad interpretation of the exceptions to preemption, particularly ''other public health purposes or health oversight purposes'' could require applicable manufacturers and applicable GPOs to report the same information to States, as well as the Federal program. These commenters recommended that CMS clarify these terms to prevent them from being interpreted so broadly to not allow for any preemption.

Response: We appreciate the comments and acknowledge that the statute seems to provide that preemption of State or local transparency and disclosure laws is effective for payments or other transfers of value made on or after January 1, 2012. We understand that the delay in publication of the rule implementing section 1128G of the Act, which was to be published by October 1, 2011, has led to uncertainty regarding when preemption actually becomes effective. We urge manufacturers to continue to report under State or local disclosure laws until the requirements under the Federal rule take effect.

We also seek to provide some additional guidelines to clarify the preemption requirements; however, we note that preemption determinations will need to be analyzed on a case-by-case basis.

We interpret ''type of information'' for purposes of the preemption clause at 1128G(d)(3)(A) of the Act, to refer to the categories of information for each payments or other transfer of value required to be reported under the statute at 1128G(a)(1)(A)(i) through (viii) of the Act and § 403.904(c) of the regulations. We believe this is consistent with the statutory exception from preemption in section 1128G(d)(3)(B)(i) of the Act pertaining to the reporting to States and localities of information not of the type required to be disclosed under Federal law. Thus, State and local entities may require reporting of nonrequired categories of information for payments or other transfers of value reported to CMS, which are not required under Federal law. This includes payment categories excluded by the Federal law (including those listed at section 1128G(e)(10)(B) of the Act), with the exception of those that do not meet the minimum dollar threshold set forth in section 1128G(e)(10)(B)(i) of the Act. In addition, States and localities may require reporting of payments or other transfers of value not required to be reported at all under the Federal law. For example, they may require the reporting of payments to non-covered recipients or by nonapplicable manufacturers. We believe this is consistent with the statutory exceptions from preemption in section 1128G(d)(3)(B)(iii) of the Act.

Finally, we understand the concern over other public health and oversight activities; however, this language is required by statute, so we cannot expressly change it. However, these exceptions cannot be used to avoid preemption. If a Federal, State or local government agency seeks to collect information reportable under this regulation for public health and/or oversight purposes and specifically needs the information for a purpose other than transparency, then such collection will not be preempted. However, if the purpose of the collection does not meet this exception and in actuality seeks to achieve the same transparency goal as the collection required under section 1128G of the Act, we believe such a collection would be preempted, and the States or localities can obtain the information they want from the Federal program.

We have finalized the proposed discussion of public health agencies. We intend such agencies to include those that are charged with preventing or controlling disease, injury or disability and/or with conducting oversight activities authorized by law, including audits, investigations, inspections, licensure or disciplinary actions, or other activities necessary for oversight of the health care system.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. The information collections contained in this rulemaking are numerous and somewhat complex. We plan to obtain approval for the information collections in a step-wise fashion as we develop our system for receiving and displaying the required information and for allowing covered recipients and physician owners or investors to review the reported data prior to display on our Web site. Below, we provide an outline of the information collections and the current status of our requests for OMB approval.

A. Recordkeeping and Reporting of Payments or Other Transfers of Value and Physician Ownership and Investment Interests (§ 403.904, § 403.906, § 403.908(a),(b),(d),(f) and (g), § 403.912(e))

Section 403.904 requires applicable manufacturers of covered drugs, devices, biologicals, and medical supplies to report annually to CMS all payments and other transfers of value to physicians and teaching hospitals (collectively, covered recipients). This includes special reporting rules for research-related payments. Section 403.906 requires applicable manufacturers and applicable GPOs to report ownership and investment interests held by physicians or the immediate family members of physicians in such entities. This information is to be aggregated and posted publicly by CMS on a searchable Web site. Annually, under § 403.908(g) applicable manufacturers and applicable GPOs will be able to review and correct the data provided in any reporting period during the 45 day period to review and correction period. Under § 403.912(e), applicable manufacturers and applicable GPOs must retain records to support their reports for 5 years from the date when the information is publicly posted on the CMS Web site. This is, in some cases, a recordkeeping requirement of at most about 9 years for payments or other transfers of value eligible for delayed publication. In our proposed rule, we requested comment on the information required in the proposed regulation, but did not include all the data elements we expected applicable manufacturers and applicable GPO's to report, nor did we include detailed information about the mechanism for submission, amendment, or correction. For this reason, we are publishing a 60-day notice elsewhere in today's **Federal Register** seeking public comment on the information collection. As part of the process, we will be seeking public comment on templates that contain the data specifications for the system we will be building.

B. Registration for Applicable Manufacturers and Applicable GPOs (§ 403.908(c))

As required by § 403.908(c), any applicable manufacturer or applicable GPO that is required to report under this subpart must register with CMS within 90 days of the end of the calendar year for which a report is required. During registration, two points of contact must be provided, as well as other information. Registration is required once, but upon filing the annual reports the system will prompt applicable manufacturers and applicable GPOs to confirm that the registration information (for example, points of contact) is still accurate. If it is not accurate, the applicable manufacturers and applicable GPOs will be prompted to provide updated information. We have yet to seek OMB approval for the information collections associated with these provisions. We plan to seek public comment consistent with the requirement of the Paperwork Reduction Act and request OMB approval at a later date. Consistent with 5 CFR part 1320, these provisions will not be effective until OMB approves the collection of information.

C. Attestation (§ 403.908(e))

As required by § 403.908(e), each report, including corrections, must include a certification that the information reported is timely, accurate, and complete. We have yet to seek OMB approval for the information collections associated with these provisions. We plan to seek public comment consistent with the requirement of the Paperwork Reduction Act and request OMB approval at a later date. Consistent with 5 CFR part 1320, these provisions will not be effective until OMB approves the collection of information.

D. Assumptions Document (§ 403.908(f))

Under (§ 403.908(f)), applicable manufacturers and applicable GPOs may submit an assumptions document with their reports. This document can set out the assumptions and methodologies used to produce the reports. It will not be made available to the public, covered recipients or physician owners or investors, but it will provide CMS with information to help identify areas where additional guidance and clarity is needed. This is a voluntary collection and CMS does not plan to request that it be submitted in any particular way. We have yet to seek OMB approval for the information collections associated with these provisions. We plan to seek public comment consistent with the requirement of the Paperwork Reduction Act and request OMB approval at a later date. Consistent with 5 CFR part 1320, these provisions will not be effective until OMB approves the collection of information.

E. Information Collections Regarding Review and Correction by Physicians and Teaching Hospitals (§ 403.908(g))

As required by section 1128G of the Act, applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors must have an opportunity to review and submit corrections to the information submitted for a period of not less than 45-days before CMS makes the information available to the public. To accomplish this review, we plan to ask covered recipients and physician owners and investors that would like to review the information to register with CMS using the CMS Enterprise Portal and associated identity and access management system. Once registered, they will be able to access a secure Web site that allows them to submit or review data securely. We have yet to seek OMB approval for the information collections associated with these provisions. We plan to seek public comment consistent with the requirement of the Paperwork Reduction Act and request OMB approval at a later date. Consistent with 5 CFR part 1320, these provisions will not be effective until OMB approves the collection of information.

F. Notice of Resolved Disputes by Applicable Manufacturers and Applicable GPOs (§ 403.908(g)(4))

Under § 403.908(g)(4), applicable manufacturers and applicable GPOs must notify CMS of resolved disputes. We have not yet established the content or form of this notice, and therefore we have yet to seek OMB approval for the information collections associated with these provisions. We plan to seek public comment consistent with the requirement of the Paperwork Reduction Act and request OMB approval at a later date. Consistent with 5 CFR part 1320, these provisions will not be effective until OMB approves the collection of information.

G. Notice of Errors or Omissions (§ 403.908(h))

Under § 403.908(h), applicable manufacturers and applicable GPOs must notify CMS immediately upon discovering errors or omissions in their reports. We have not yet established the content or form of this notice, and therefore we have yet to seek OMB approval for the information collections associated with these provisions. We plan to seek public comment consistent with the requirement of the Paperwork Reduction Act and request OMB approval at a later date. Consistent with 5 CFR part 1320, these provisions will not be effective until OMB approves the collection of information.

IV. Regulatory Impact Analysis

A. Statement of Need

This final rule is necessary to implement the requirements in section 1128G of the Act (as added by section 6002 of the Affordable Care Act), which requires applicable manufacturers of covered drugs, devices, biologicals, and medical supplies to report annually to the Secretary all payments and other transfers of value to physicians and teaching hospitals (collectively, covered recipients). Section 1128G of the Act also requires applicable manufacturers and applicable GPOs to report ownership and investment interests held by physicians or the immediate family members of physicians in such entities.

These provisions of the Act were modeled largely on the recommendations of the MedPAC, which voted in 2009 to recommend Congressional enactment of a new regulatory program. The problem addressed, as stated by MedPAC, is that ''at least some'' drug and device manufacturer interactions with physicians ''are associated with rapid prescribing of new, more expensive drugs and with physician requests that such drugs be added to hospital formularies,'' as well as ''concern that manufacturers' influence over physicians' education may skew the information physicians receive.'' MedPAC went on to say that ''there is no doubt that those relationships should be transparent,'' while pointing out that ''transparency does not imply that all—or even most—of these financial ties undermine physician-patient relationships.'' [5] While a few comments discussed the reliability of the data used for the MedPAC report, we believe that the overall conclusions of the report are valid and continue to see the report's findings as a reason to promote transparency.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and promoting flexibility. Section 4 of Executive Order 13563 calls upon agencies to consider approaches that ''maintain flexibility and freedom of choice for the public,'' including the ''provision of information to the public in a form that is clear and intelligible.'' A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold. Accordingly, we have prepared a Regulatory Impact Analysis that presents estimated costs and benefits of the rulemaking. We solicited comments on all assumptions and estimates in this regulatory impact analysis, including some assumptions and estimates that were presented in the Collection of Information Requirements section of the proposed rule. As is standard practice in

[5] All quotes from pages 315–316 of ''Public reporting of physicians' financial relationships'' at *http://www.medpac.gov/chapters/Mar09_Ch05.pdf.*

meeting these various requirements for regulatory analysis, this section of the final rule addresses all of them together.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. Under the RFA, ''small entities'' are those that fall below size thresholds set by the Small Business Administration, or are not-for-profit organizations or governmental jurisdictions with a population of less than 50,000. We did not receive any comments on these aspects of the RFA, so have finalized it as proposed. For purposes of the RFA, we estimate that the majority of teaching hospitals and physicians, and most applicable manufacturers and applicable GPOs are small entities under either the size or not-for-profit standard. According to the Small Business Administration size standards [6] the threshold size standard for ''small'' pharmaceutical manufacturers is 750 employees, for biological products, and surgical equipment, surgical supplies, and electromedical/electrotherapeutic apparatus manufacturers is 500 employees and for drug and medical equipment wholesalers is 100 employees. We estimate that approximately 75 percent of applicable manufacturers and applicable GPOs are smaller than these size standards. In this final rule, we assume that applicable manufacturers that do not have payments or other transfers of value or physician ownership or investment interests to report do not need to submit a report. We believe that many small applicable manufacturers and applicable GPOs will have no relationships, thus will not have to report, so the burden on them will be negligible. For small entities with financial relationships to report, we believe that they will only have a small number to report, making the reporting process significantly less burdensome. We believe that the average burden of the reporting requirements will be about $80,000 in the first year (the sum of 0.25 FTEs of compliance officer at $48 hourly rate and 1 administrative support FTE at $26 hourly rate times 40 hours and 52 weeks) for smaller manufacturers, and even less in subsequent years. This amount is far below the 3 percent of revenues that HHS uses as a threshold for ''significant impact'' under the RFA, so these regulations will not have a significant effect on these small entities. For example, if a firm with only 100 employees generates annual revenues of $200,000 per employee, or $20 million, a cost of $80,000 would be less than 0.5 percent of the revenues. Firms this small would potentially face costs considerably less than $80,000, and hence an even lower effect.

As previously noted, most teaching hospitals and physicians are small entities under the RFA, since most teaching hospitals are not-for-profit and some have revenues below $34.5 million. We estimate that 95 percent of physician practices have revenues under $10 million. We believe the regulatory effects of this provision on physicians and teaching hospitals are relatively minor. Physicians and teaching hospitals are provided with the opportunity to review and correct this information, but are not involved in the data collection or reporting processes. We estimated that this review would take 1 hour from the individual physicians and 5 hours for the supporting staff to perform the duty to maintain records and review the reports annually. For teaching hospitals, it is estimated that on average 40 hours of compliance officer and 80 hours of supporting staff would needed. Given that their review will take such a small amount of their time annually, the costs faced by physicians and teaching hospitals are not substantial. As a result, we believe that the cost burden of this review and correction period will be far below the 3 percent threshold for ''significant impact.'' Therefore, we have determined that this proposed rule will not have a significant economic impact on a substantial number of small entities in any category of entities it affects.

In addition, as stated in the proposed rule, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. In the proposed rule, we stated that we did not believe that any of the affected teaching hospitals are small rural hospitals, so did not believe that the rule had a significant impact on the operations of small rural hospitals. We did not receive any comments on this, so we have determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any single year of $100 million in 1995 dollars, updated annually for inflation. In early 2013, that threshold is approximately $139 million. The estimates presented in this section of this rule exceed this threshold and as a result, we have provided a detailed assessment of the anticipated costs and benefits in section V.C.4. of this final rule. Reporting under section 1128G of the Act is required by law, so we are limited as to policy options. Section IV.D. of this final rule, as well as other parts of the preamble, provide detailed additional information on the alternatives we considered.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. While this final rule does preempt certain elements of State law, the regulatory standard simply follows the express preemption provision in the statute. Because of this and the fact that this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable. We offer a more detailed discussion of preemption in § 403.914 of this final rule.

C. Anticipated Effects

The regulatory impact of this provision includes applicable manufacturers and applicable GPOs collection and submitting this information to CMS, and physician and teaching hospital review and correction period. The costs of these requirements are outlined in section III. of this final rule. We estimate a total cost of about $269 million for the first year of reporting, followed by about $180 million in the second year and annually thereafter.

1. Effects on Applicable Manufacturers and Applicable GPOs

For applicable manufacturers, only those that made reportable payments or other transfers of value, or have physicians (or immediate family members of physicians) holding ownership and investment interests, will be required to submit reports. Similarly, only applicable GPOs that have ownership or investment interests held by physicians (or immediate family members of physicians) would be required to submit reports. We estimate that approximately 1,150 applicable

[6] *http://www.sba.gov/sites/default/files/Size_Standards_Table.pdf.*

manufacturers, (150 drug and biologic manufacturers, and 1,000 device and medical supply manufacturers), and approximately 420 applicable GPOs would submit reports. We based these estimates on the number of manufacturers reporting in States with similar transparency provisions, as well as the number of manufacturers registered with FDA. The number of drug manufacturers is based on reporting in Massachusetts, Minnesota, and Vermont, whereas the number of device manufacturers is based on reporting in Massachusetts and Vermont, since Minnesota does not require device manufacturers to report. Because the State laws have higher payment thresholds and are specific to the physicians in the State, we estimated that the number of manufacturers reporting would be greater under section 1128G of the Act, so we increased the State reporting numbers by 50 percent. For device manufacturers, we also used data from the FDA to identify the total number of manufacturers to use as a ceiling for our estimate, combining the two data sources we increased the State reporting numbers by 75 percent. We believe that device manufacturers are often smaller and more region specific, which is why we increased the State estimates by a greater percentage. We did not receive comments on the number of reporting entities, except for information on the number of device manufacturers reporting in Vermont, where the legislature amended the transparency scheme in 2009 to include reporting by device manufacturers, so have finalized these assumptions.

It is difficult to establish with precision the number of GPOs, as proposed, because the definition of GPO includes some physician owned distributorships (PODs). However, we did rely on a recent report by the Senate Finance Committee which identified 20 States with multiple PODs and more than 40 PODs in California.[7]. When we extrapolate these estimates to the national level, taking into account the disproportionately higher number in California, we estimate that there are approximately 260 PODs currently in the U.S. We further estimate that there are an additional 160 GPOs, which have some form of physician ownership or investment. This is based on a review of what little literature exists and discussions with knowledgeable persons. Our research found that there are approximately 800 GPOs and that approximately 20 percent of GPOs have at least one physician owner or investor. We did not receive comments on the number of GPOs, so have finalized these assumptions.

In the public comments, we received comments on the estimated costs of the reporting requirements, but not the individual activities associated with them. Given these comments, we have revised the estimates, but have not revised the activities the FTEs will be required to perform, since we believe they accurately portray the requirements. Coordinating the data collection will require ensuring that all payments and other transfers of value are attributed to the correct covered recipient and reported in the manner required in this final rule. These estimates include our aggregate estimate of the overall time required to build and maintain the reporting systems (including the development of new information technology systems), train appropriate staff, obtain NPI and other information from the NPPES system (and if necessary supplement that information), establish whether any owners or investors have physicians as immediate family members (if necessary), organize the data for submission to CMS (within the organization and with any third party vendors), register with CMS and submit the required data, review the aggregated data that CMS produces, respond to any physician or teaching hospital queries during the review process, and resubmit and re-attest to certain disputed information (if necessary). Finally, it also includes any time required to maintain records, as required. However, we believe that much of this information will be collected and stored already for financial reasons, so we do not anticipate a significant burden. It allows for time applicable manufacturers and applicable GPOs may sometimes use for ''pre-submission'' reviews but assumes that would be rarely used, and only for complex cases. It also includes the time that applicable manufacturers may elect to spend to submit with their data a document describing their assumptions and methodology for categorizing the nature of payments. The estimates also include a downward adjustment to reflect the potential time savings that would accrue to applicable manufacturers who register with the CMS system and thus have the ability to query CMS, receive informal guidance through a listserv or other methods of providing technical assistance, and ultimately obtain useful information on low cost methods of compliance.

Comment: Several commenters stated that the current cost estimation for applicable manufactures and applicable GPOs to comply with the reporting requirements are too low, and CMS should increase the FTE estimates.

Response: We agree with the comment and have increased our estimates of the average FTE burden associated with the manufacturer and GPO reporting requirements. However, we believe that applicable manufacturers and applicable GPOs vary in their readiness to comply with the reporting requirements. Some companies have existing reporting systems in place, which can be used to comply with the government requirements. These systems track the wide range of financial interactions between the company, and physicians and teaching hospitals. Additionally, the efforts and workload varies with the size of the company as larger manufacturers will have more transactions, so may need more FTEs accordingly. As in the proposed rule, we estimated the impact based on all sizes of companies, recognizing that there are a few very large companies for which this would be a low estimate, but there are small companies which may need fewer FTEs. Additionally, we also took into account the finalized provisions that applicable manufacturers with less than 10 percent of gross revenues coming from covered products would only have to report payments or other transfers of value related to covered products, rather than all products. This will greatly reduce the reporting burden for these manufacturers, so we have considered them small companies for reporting purposes. Finally, we separated the FTE estimates to include a full time compliance officer, as well as multiple support staff for bookkeeping, accounting, and auditing; this change in approach yields a lower average cost per FTE than we estimated in the PRA.

We estimate that, for year 1, on average, smaller applicable manufacturers will have to dedicate 25 percent of an FTE employee (mainly in the range of zero to 50 percent), whereas larger applicable manufacturers may have to dedicate 1 to 10 FTE employees to comply with the reporting requirements (we assume 2 FTEs on average). Furthermore, we estimated that reporting activities will be conducted by the managerial staff and supporting staffs, the compliance or similar level of staffs will oversee the reporting activities, which will largely be supported by staff involved with bookkeeping, accounting and auditing. Since there are many more small companies, we estimate that on average, 0.5 FTEs of compliance officer and 2 FTEs of supporting staff would be needed for each applicable manufacturer in the first year (2 FTEs of

compliance officer and 8 FTEs of supporting staffs in 150 larger firms and 0.25 FTEs of compliance officer and 1 FTE of supporting staffs in 1,000 smaller firms). We appreciate that this is considerable simplification of a far more complex distribution of firms, but we believe that it captures the distribution in manufacturing sectors where a relative handful of firms have sales in the billions of dollars annually over a wide range of products, and a far larger number have annual sales in low millions of dollars annually for just a few products, with practices regarding financial relationships with physicians varying widely within each group and, in many cases by product or product class.

Therefore, for applicable manufacturers, the revised cost estimation assumes a compliance officer (0.5 full-time equivalents (FTEs)) and 2 FTEs of bookkeeping, accounting and auditing staff support in the first year. In the second year and thereafter, we reduced the estimates, since we believe the system will be more automated. In year 2 and thereafter we assumed 0.375 FTEs (780 hours) of a compliance officer and 1.5 FTEs (3,120 hours) of bookkeeping, accounting, and auditing support. Compared with the estimates we provided in the proposed rule, the total first-year FTE increased from 1.74 to 2.5 FTEs for applicable manufacturers. It should be noted that this is an average cost while the large manufacturers may need more and the small manufacturers may need less FTEs.

The greater staff time for year 1 represents time for applicable manufacturers to alter their systems to collect and report this data. We estimate that once procedures and systems are modified, costs would be 25 percent lower, which reduces this value to an average of 0.375 FTEs of compliance officer and 1.5 FTEs of support staff in year 2 and annually thereafter. We emphasize that these are very rough estimates. The actual burdens could easily average 25 percent lower or higher, and would depend on manufacturers' changes in practices after the regulations are made final. Some may welcome the new transparency; others may decide to change or eliminate their current practices. Our assumption that smaller firms could in some cases incur no new costs assumes that some do not now have any such financial relationships and that this proportion would grow as some firms decide that the benefits of such relationships are less than the costs of reporting. Other smaller firms with only a few products and only a few financial relationships might well already have systems in place that essentially meet the proposed requirements or that could do so with minimal effort.

We anticipate it would be less burdensome for an applicable GPO to comply with these proposed reporting requirements, since we believe companies will have fewer relationships with physician owners or investors (or immediate family members). This will make it much easier for applicable GPOs to match ownership and investment interests to the appropriate physicians (or family members). Based on discussions with officials of some GPOs and industry observers, we estimate that it would take from 5 to 25 percent of a FTE staff member, depending on the size of the applicable GPO. We assume that applicable GPOs already know the ownership and investment interests of its major investors, so the burden of these requirements include any changes to internal procedures to record and report the information. Also again, we have not found any empirical studies to better inform this estimate. Accordingly, we estimate that on average, an applicable GPO would dedicate 10 percent of an FTE (208 hours) of compliance officer and 0.25 FTEs (520 hours) of support staff to reporting under this section for year 1, followed by 25-percent reductions in both the compliance officer's time and support staff's time for year 2 and annually thereafter. Compared with the estimates we provided in the proposed rule, the total first-year FTE estimates increased from 0.1 FTE (208 hours) to 0.35 (728 hours) for GPOs.

While many individuals within the applicable manufacturer or applicable GPO may contribute to the data collection and reporting, we believe that majority of the work will be performed by the support staff and overseen by a compliance officer. According to the Bureau of Labor Statistics Occupational Employment Statistics, in May 2011, the average hourly rates for a compliance officer and bookkeeping, accounting and auditing staff in the pharmaceutical and medicine manufacturing field was $35.75 and $19.84, respectively. We applied a 33 percent increase to this amount to account for fringe benefits, making the total hourly compensation $47.55 and $26.39, respectively. The total number of hours for applicable manufacturers (including the hours for compliance officers and support staff) during year 1 would be 5,980,000 (1,150 applicable manufacturers × 100 hours (2.5 FTEs) × 52 weeks). For year 2 and subsequent years, we estimate a total of 4,485,000 hours (1,150 applicable manufacturers × 75 hours (1.875 FTEs) × 52 weeks). On average, this equals 4,983,333 hours annually for all applicable manufacturers for the first 3 years. The total number of hours for applicable GPOs (including the hours for compliance officers and support staff) for year 1 would be 305,760 (420 applicable GPOs × 14 hours (0.35 FTE) × 52 weeks) and for year 2 would be 229,320 hours (420 applicable GPOs × 10.5 hours (0.2625 FTEs) 52 weeks). For the first 3 years in total, applicable GPOs will spend on average 254,800 hours annually.

The following tables provide our total cost estimates for applicable manufacturers and applicable GPOs to comply with the data collection requirements in section 1128G of the Act such as collecting information, responding to inquiries, developing reports, and submitting reports to CMS. In total, we estimate that for applicable manufacturers and applicable GPOs required to report, it will cost $193,037,104 for year 1 and will cost $144,777,828 for year 2 and annually thereafter. For the first 3 years, this averages to a cost of $160,864,253 annually. All estimates are in 2011 dollars.

We note that Tables 1A and 1B contain revised estimated labor costs. The original cost estimates were included in the December 19, 2011 proposed rule (76 FR 78742).

TABLE 1A—YEAR 1 ESTIMATED LABOR COSTS FOR APPLICABLE MANUFACTURERS AND APPLICABLE GPOS

	Estimated reporting organizations	Estimated hours per reporting organization	Hourly rate	Average total cost per organization	Total cost
Compliance officer in AM	1,150	1,040	$48	$49,452	$56,869,800
Supporting staffs in AM	1,150	4,160	26	109,782	126,249,760
Compliance officer in Applicable GPOs	420	208	48	9,890	4,153,968

TABLE 1A—YEAR 1 ESTIMATED LABOR COSTS FOR APPLICABLE MANUFACTURERS AND APPLICABLE GPOS—Continued

	Estimated reporting organizations	Estimated hours per reporting organization	Hourly rate	Average total cost per organization	Total cost
Supporting staffs in Applicable GPOs	420	520	26	13,723	5,763,576
Total					193,037,104

TABLE 1B—YEAR 2 AND SUBSEQUENT YEAR ESTIMATED LABOR COSTS FOR APPLICABLE MANUFACTURERS AND APPLICABLE GPOS

[Annual]

	Estimated reporting organizations	Estimated hours per reporting organization	Hourly rate	Average total cost per organization	Total cost
Compliance officer in AM	1,150	780	$48	$37,089	$42,652,350
Supporting staffs in AM	1,150	3,120	26	82,337	94,687,320
Compliance officer in Applicable GPOs	420	156	48	7,418	3,115,476
Supporting staffs in Applicable GPOs	420	390	26	10,292	4,322,682
Total					144,777,828

In addition to FTE costs, we also assume that there would be some infrastructure costs associated with the reporting requirements under section 1128G of the Act. We acknowledge a substantial amount of uncertainty in these estimates. For example, we do not know how many companies will be using existing systems and technology to comply with the requirements and how many will be obtaining new equipment and technology; in both cases, there will be opportunity costs of using the systems for the reporting required by this rule, but with new systems, there might be higher-set-up costs. We also envision that companies of varying size will have different infrastructure needs, so have selected an average amount based on CMS infrastructure estimates of the requirements. We estimate that in year 1 the infrastructure costs for applicable manufacturers will be $10,000. This represents an average of $4,000 for small companies (estimated to be 1000 companies) and $50,000 for large companies (estimated to be 150 companies). We assume that the majority of these costs will be infrastructure costs, such as purchasing equipment and initial training, but assume that some costs will be required to maintain the systems. Therefore, we estimate that in year 2 and annually thereafter, applicable manufacturers will spend about $1,000 annually to maintain their systems. This represents 10 percent of the original infrastructure, which we believe is reasonable given CMS's experience with system maintenance. We note that this only covers the system and equipment maintenance and not the staff time to comply with the reporting requirements.

For applicable GPOs, we assume the infrastructure costs associated with the reporting requirements will be lower than that for applicable manufacturers. We assume that the applicable GPO costs will be roughly 20 percent of those for applicable manufacturers. This is based on the fact that estimated FTE costs for applicable GPOs are roughly 20 percent of that of applicable manufacturers. Therefore, we estimate that in year 1 the infrastructure costs for applicable GPOs will be $2,000. Similarly, we estimate that maintenance costs will be 10 percent of the initial cost, so in year 2 and beyond the maintenance costs for applicable GPOs will be $200. Table 2A and 2B contain the estimated infrastructure costs for applicable manufacturers and applicable GOPs in year 1 and year 2 and thereafter, respectively. We further assume that the combined infrastructure and maintenance costs per burden hour will be the same for physicians and teaching hospitals as for GPOs.

We note, and discuss in the benefits section later in this section, that the costs of applicable manufacturers may be partially offset because many companies are already required to report to States with similar disclosure requirements, but would no longer be required to report the same information to States after the final rule is issued. In addition, a few large companies are already reporting similar information on a national level in order to comply with Corporate Integrity Agreements (CIAs) with HHS OIG. These companies may not have to invest as much as we estimated earlier in this section to comply with the requirements in section 1128G of the Act. However, given the differing requirements for each State and CIA, and broad scope of section 1128G of the Act, we do not believe it is possible to approximate any lessened burden for entities already reporting.

Because applicable manufacturers have some influence in getting their products on a Part D plan formulary, obtaining billing codes, or getting Medicaid coverage, they have some control over whether Medicare, Medicaid and CHIP payments are available for their products. If applicable manufacturers were to stop accepting such payments so as to avoid reporting requirements, it would reduce the rule-induced cost that they bear themselves, but might negatively affect the well-being of Medicare, Medicaid and CHIP patients who no longer have coverage for a full range of medical products. However, because these public programs represent a very large patient population, we do not anticipate that applicable manufacturers will refrain from participating in the programs just to avoid reporting requirements.

TABLE 2A—YEAR 1 ESTIMATED INFRASTRUCTURE COSTS FOR APPLICABLE MANUFACTURERS AND APPLICABLE GPOS

	Organizations	Annual cost	Total cost
Large Applicable Manufacturers	150	$50,000	$7,500,000
Small Applicable Manufacturers	1000	4,000	4,000,000
Applicable GPOs	420	2,000	840,000
Total			12,340,000

TABLE 2B—YEAR 2 AND SUBSEQUENT YEAR ESTIMATED INFRASTRUCTURE COSTS FOR APPLICABLE MANUFACTURERS AND APPLICABLE GPOS

[Annual]

	Organizations	Annual cost	Total cost
Large Applicable Manufacturers	150	$5,000	$750,000
Small Applicable Manufacturers	1000	400	400,000
Applicable GPOs	420	200	84,000
Total			1,234,000

2. Effects on Physicians and Teaching Hospitals

We also have estimated costs for physicians and teaching hospitals, since they would have an opportunity to review and correct the data submitted by applicable manufacturers. The statute uses the definition of physician in section 1861(r) of the Act, which includes doctors of medicine and osteopathy, dentists, dental surgeons, podiatrists, optometrists and licensed chiropractors. Using the Bureau of Labor Statistics Occupational Outlook Handbook, we estimate that information may be available for as many as 897,700 physicians. However, we believe that not all physicians will have relationships with applicable manufacturers or applicable GPOs. In the proposed rule, we assumed that roughly 75 percent of physicians would have relationships. However, based on feedback we received from stakeholders, including a private firm with data of roughly 50 companies currently reporting, we now estimate that less than 50 percent of the physicians have transactions with industry. We assume that 50 percent of physicians have no relationships with applicable manufacturers or applicable GPOs, which reduces our universe of affected physicians to approximately 448,850. Further, stakeholders have expressed that many physicians maintain relationships with applicable manufacturers that are relatively insignificant from a financial point of view, so we estimate that many physicians will not devote any time to reviewing and correct the aggregated reports from CMS. We estimate that only 50 percent of the remaining 448,850 physicians will review the report, which reduces our universe of affected physicians to 224,425 for year 1. For year 2, we anticipate that there would be a further reduction in the number of physicians choosing to review the data because they would be familiar with the type of information on the database, so we reduced the number of physicians reviewing by another 25 percent, to 168,319 physicians. We also reduced the amount of time it would take the physicians choosing to review the information, since we believe they will be familiar with the review, correction and dispute process. For teaching hospitals, we know that about 1,100 hospitals receive Medicare GME or IME payments, all of which are defined as teaching hospitals for this provision. We believe that the vast majority of teaching hospitals would have at least one financial relationship with an applicable manufacturer, so we did not apply any adjustments to this estimate. We also anticipate that there would not be a reduction in the number of teaching hospitals that review the information after the first year because teaching hospitals probably have more complex financial relationships.

See the Table 3 for a breakdown of this calculation. In the proposed rule, we mistakenly omitted dental surgeons from the table, so have added estimates for them in the final rule. The definition of physician at section 1861(r) of the Act explicitly includes them.

TABLE 3—NUMBER OF PHYSICIANS BY TYPE

Physician type	Number
Doctor of Medicine/Doctor of Osteopathy	660,000
Doctor of Dental Medicine	155,700
Doctor of Podiatric Medicine	12,000
Doctor of Optometry	35,000
Licensed Chiropractors	*35,000
Total	897,700
Adjustment for Physicians with no reports (only 50% had transaction with industry)	448,850
Adjustment for Physicians who do not review reports (Year 1—reduction by 50%)	224,425
Adjustment for Physicians who do not review reports (Year 2—reduction by 25%)	168,319

* Reduced from 50,000 in BLS to account for licensure.

We received numerous comments on the cost estimations for physicians and teaching hospitals, and have responded to them and revised our cost estimates accordingly.

Comment: Several commenters questioned the time and cost estimation for physicians. Specifically, the commenters stated that the time allotted for the physicians to review the data is too short, since physicians will need to maintain records in order to review the information submitted on their behalf accurately. Similarly, several commenters noted that the current hourly rate for the physician ($75) is low.

Response: We agree with commenters that the physicians and teaching hospitals may need to maintain ongoing records of the activities for verification purposes, so have increased the time dedicated to the physician and teaching hospital review. However, we assume that most of these recordkeeping activities will fall on the duty of the office assistants, but the physician may need to review the records. The hours of bookkeeping are added in the revised cost estimation for physician and teaching hospital accordingly. Additionally, we agree that the physician hourly rate should be increased. The hourly rate for physicians in the final rule is updated to $137 per hour, which is based on the most recent data from Bureau of Labor Statistics (BLS).

Comment: A few commenters questioned CMS's cost estimate of 10 hours of compliance officer in teaching hospitals, which state that teaching hospitals will need more time to review the transactions and maintain records to facilitate the review.

Response: We agree with commenters that teaching hospitals will likely need more time for their review. The hospital compliance officer's annual hours have been increased from 10 hours to 40 hours. In addition, we revised the cost estimation to include 80 hours of administrative supporting staff at teaching hospitals to maintain the records. The role of the compliance officer will be review and oversight, while the administrative supporting staff will conduct the recordkeeping.

In response to the comments, even though there is no requirement for physician and teaching hospitals to review the reports or maintain records of interaction, we estimated the covered recipients may maintain records to facilitate reviews. In the final rule, we estimated the supporting staffs such as bookkeeping, accounting, and auditing would perform the tasks while the compliance officer would oversee the review process.

When reviewing the information reported, physicians and teaching hospitals are allowed to review the information attributed to them by applicable manufacturers and applicable GPOs that submitted data to CMS. A number of commenters suggested that physicians and teaching hospitals would spend some time during the year maintaining records to facilitate their review. In response to this feedback, we added estimates for recordkeeping for physicians and teaching hospitals and assumed that support staff would perform these functions. We estimate that on average, physicians would need 1 hour annually to review the information reported. For physicians that choose to review the information, this would range from a few minutes for physicians with few relationships with applicable manufacturers, to at most 10 or 20 hours for the small number of physicians who have lengthy disputes over a payment or other transfer of value, or ownership or investment interest. In addition, we also estimated 5 hours annually of supporting staff for each physician to help them to maintain records to facilitate the review. We believe that teaching hospitals will have to review more payments or other transfers of value and have more complex relationships, so we estimate that, on average, it would take a representative, such as a compliance officer, from a teaching hospital 40 hours annually to review the submitted data, ranging from 10 hours for small teaching hospitals that receive few payments or other transfer of value, to 200 hours for teaching hospitals that have lengthy disputes. In addition, we also estimated 80 hours annually of administrative support staff for each teaching hospital to help them maintain their records.

The Bureau of Labor Statistics Occupational Employment Statistics publishes data on hourly compensation for Healthcare Practitioners and Technical Occupations in physicians' offices. The average hourly rate for physicians and surgeons is $103.32,[8] which rises to $137 with 33-percent fringe benefits. This average includes physicians, who account for about half of the employment in this category. In the proposed rule, we used an estimate for the hourly wage that included other provider types, but having received numerous comments that the resulting wage was too low, we increased the estimate for this final RIA. The average hourly rate for the supporting staff is $16.35 which rises to $21.75 with 33 percent fringe benefits. The total number of hours for physicians (including supporting staffs in physician offices) would be 1,346,550 (224,425 × 6 hours) for year 1 and 757,436 hours (168,319 × 4.5 hours) for year 2, which averages to 953,807 hours annually for the first 3 years. The total estimated cost for the review and correction period for physicians and the supporting staffs in year 1 is $55,152,444. For year 2 and annually thereafter, the estimated cost for physician and supporting staffs to conduct review and correction is $31,023,250. For the first 3 years, the average cost for all physicians review and correction will be $39,066,314 annually.

For teaching hospitals, as explained, we expect a compliance officer to review the payments and other transfers of value with supporting staff to maintain any necessary records. Since this review could be done by employees with multiple titles, we used the Bureau of Labor Statistics Occupational Employment Statistics reported compensation for Management Occupations at General Medical and Surgical Hospitals in 2010. The hourly average rate for compliance officer in hospitals is $32.94 or $43.81 when fringe benefit costs are applied. The average hourly rate for the supporting staff in a teaching hospital is $16.22 which rises to $21.57 with 33 percent fringe benefits. For year 1, the total number of hours would be 132,000 (1,100 × 120 hours). For year 2 this would decrease to 99,000 hours (1,100 × 90 hours). For the first 3 years, the average number of hours for teaching hospitals will be 110,000 annually. The total estimated cost for the review and correction period for teaching hospitals is $3,825,800 for year 1 and $2,869,350 for year 2 and annually thereafter. On average, the cost for all teaching hospitals will be $3,188,167 annually for the first 3 years.

We note that Tables 4A and 4B contain revised cost estimates. The original cost estimates were included in the proposed rule (76 FR 78742).

[8] *http://www.bls.gov/oes/current/naics4_621100.htm.*

TABLE 4A—YEAR 1 ESTIMATED COSTS FOR PHYSICIANS AND TEACHING HOSPITALS

	Estimated number of entities reviewing	Estimated hours for review	Hourly rate	Average total cost per entity	Total cost
Physicians	224,425	1.00	$137	$137	$30,746,225
Physicians Support staffs	224,425	5.00	22	109	24,406,219
Compliance officer, Teaching Hospitals	1,100	40.00	44	1,752	1,927,640
Administrative supporting staffs in teaching Hospitals	1,100	80.00	22	1,726	1,898,160
Total					58,978,244

TABLE 4B—YEAR 2 AND SUBSEQUENT YEAR ESTIMATED COSTS FOR PHYSICIANS AND TEACHING HOSPITALS

[Annual]

	Estimated number of entities reviewing	Estimated hours for review	Hourly rate	Average total cost per entity	Total cost
Physicians	168,319	0.75	$137	$103	$17,294,751
Physicians Support staffs	168,319	3.75	22	82	13,728,498
Compliance officer, Teaching Hospitals	1,100	30.00	44	1,314	1,445,730
Administrative supporting staffs in teaching Hospitals	1,100	60.00	22	1,294	1,423,620
Total					33,892,600

For purposes of analysis, we also include estimates of the infrastructure costs for physicians and teaching hospitals, which may need to purchase and maintain equipment for internal tracking purposes. We assume that the combined infrastructure and maintenance costs for teaching hospitals will be the same as those for GPOs. For physicians, we assume a total cost of $2 million in the first year, and 10 percent thereafter.

TABLE 5A—YEAR 1 ESTIMATED INFRASTRUCTURE COSTS FOR PHYSICIANS AND TEACHING HOSPITALS

	Number	Annual cost	Total cost
Physicians	224,425		$2,000,000
Teaching Hospitals	1,100	2,000	2,200,000
Total			4,200,000

TABLE 5B—YEAR 2 AND SUBSEQUENT YEAR ESTIMATED INFRASTRUCTURE COSTS FOR PHYSICIANS AND TEACHING HOSPITALS

	Number	Annual cost	Total cost
Physicians	168,319		$200,000
Teaching Hospitals	1,100	$200	220,000
Total			420,000

3. Effects of Third Parties

We also received some comments on including estimates for entities that were not included in the proposed rule. We have provided the comment, as well as our response.

Comment: Many commenters suggested that the costs of recordkeeping for third parties, such as contract research organizations or professional associations that receive indirect payments or other transfers of value, should be included in the cost estimation.

Response: In the final rule, we have clarified the requirements for third parties which received payments at the request of, or on behalf of, covered recipients (§ 403.904(c)(10)), as well as the requirements for third parties which receive and make indirect payments to covered recipients (§ 403.904(i)(1)). We believe these revisions will help clarify and minimize any reporting requirements that third parties viewed as burdensome to them, but we maintain that the requirements in section 1128G of the Act do not impose significant burden on third parties, since they are neither required to report nor review. However, we recognize that some business models may require third parties to report recipients of payments back to applicable manufacturers, so we have included in the final rule estimates on the burden for third parties. We estimate that 58 third parties will incur costs under this final rule. We assume that there will be significantly fewer third parties than applicable manufacturers affected by these provisions, so we reduced the number of applicable manufacturers by 95 percent to obtain the number of third

parties as 5 percent the number of applicable manufacturers. Given the range of entities that could be third parties, we believe it is difficult to estimate the hourly rate for these entities. We assume that the role will be similar to that of compliance officers in applicable manufacturers and applicable GPOs, since it may require them to track similar relationships. Therefore, we estimate the hourly rate for third parties will be $47.55 ($35.75, plus a 33 percent increase for fringe benefits), which is the same hourly rate described in section IV.C.1. the final rule for a compliance officer at an applicable manufacturer or applicable GPO. As described, we do not believe these requirements set significant burden on third parties, since they are neither required to report nor review. We estimate that third parties may need to spend 40 hours in year 1 on tasks that are associated with the reporting requirements. Similarly to other estimates, we decreased this estimate by 25 percent in year 2 (for a total of 30 hours) to account for increased familiarity with the systems. In total, third parties will dedicate 2,320 hours in year 1 and 1,740 hours in year 2 with a total cost of $110,316 in year 1 and $82,737 in year 2.

In summary, the first year and subsequent year annual costs are presented in the following tables.

TABLE 6A—TOTAL YEAR 1 ESTIMATED COSTS

	Labor costs ($)	Infrastructure costs ($)	Total cost ($)
Applicable Manufacturers	183,119,560	11,500,000	194,619,560
Applicable GPOs	9,917,544	840,000	10,757,544
Third-Parties	110,316	.....	110,316
Physicians	55,152,444	2,000,000	57,152,444
Teaching Hospitals	3,825,800	2,200,000	6,025,800
Total	252,125,664	16,540,000	268,665,664

TABLE 6B—TOTAL COSTS, YEAR 2, AND SUBSEQUENT YEARS

[Annual]

	Labor costs ($)	Infrastructure costs ($)	Total cost ($)
Applicable Manufacturers	137,339,670	1,150,000	138,489,670
Applicable GPOs	7,438,158	84,000	7,522,158
Third-Party Recordkeeping	82,737	.....	82,737
Physicians	31,023,250	200,000	31,223,250
Teaching Hospitals	2,869,350	220,000	3,089,350
Total	178,753,165	1,654,000	180,407,165

4. Effects on the Medicare, Medicaid, and CHIP

Although the Department proposes to administer this program through the CMS, the final rule would have no direct effects on the Medicare, Medicaid, and CHIP. Reporting is required for physicians and teaching hospitals regardless of their association with Medicare, Medicaid, or CHIP. Manufacturers are identified by whether the company has a product eligible for payment by Medicare, Medicaid or CHIP, but this does not affect whether or not the product may be covered under titles XVIII, XIX, or XXI of the Act. We will incur some costs in administering the program. However, as required by statute, we will be able to use any funds collected from the CMPs assessed under this rule to support the program, decreasing the agency funding required.

5. Benefits

We outlined numerous benefits in the proposed rule and received numerous comments supporting these benefits. We appreciate these comments. Collaboration among physicians, teaching hospitals, and industry manufacturers can contribute to the design and delivery of life-saving drugs and devices. While collaboration is beneficial to the continued innovation and improvement of our health care system, some payments from manufacturers to physicians and teaching hospitals can introduce conflicts of interests that may influence research, education, and clinical decision-making in ways that compromise clinical integrity and patient care, and lead to increased program costs. It is important to understand the extent and nature of relationships between physicians, teaching hospitals, and industry manufacturers through increased transparency, and to permit patients to make better informed decisions when choosing health care professionals and making treatment decisions. Additionally, it is important to develop a system that encourages constructive collaboration, while also discouraging relationships that threaten the underlying integrity of the health care system.

Both the Institute of Medicine and other experts, such as MedPAC, have noted the recent increases in both the amount and scope of industry involvement in medical research, education, and clinical practice has led to considerable scrutiny and recommended enhanced disclosure and transparency to discourage the inappropriate use of financial incentives and lessen the risk of such incentives interfering with medical judgment and patient care. We recognize that disclosure is not sufficient to differentiate beneficial, legitimate financial relationships from those that create a conflict of interest or are otherwise improper. However, transparency can shed light on the nature and extent of relationships, and

discourage inappropriate conflicts of interest.[9]

We have no empirical basis for estimating the frequency of such problems, the likelihood that transparent reporting will reduce them, or the likely resulting effects on reducing the costs of medical care. Although a few States do have similar reporting requirements, determining the benefits based on their experiences is difficult. Transparency does not identify which relationships are conflicts of interests or whether public reporting dissuaded a relationship from forming, making it difficult to assess the benefits of public reporting. We plan to continue considering methods to use the data collected to identify any changes in these relationships as a result of public reporting. However, we observe, that the costs for preparing reports are small in relation to the size of the affected industry sectors.

Finally, section 1128G(d)(3) of the Act preempts State laws requiring the reporting of the same type of information as required by section 1128G(a) of the Act. Applicable manufacturers and applicable GPOs subject to State requirements would not have to comply with multiple State requirements, and instead would only have to comply with a single Federal requirement with regard to the types of information required to be reported under 1128G(a) of the Act. This benefits applicable manufacturers and applicable GPOs by allowing them to comply with a single set of reporting requirements for this information, lessening the potential for multiple, conflicting State requirements. This benefit may also lead to potential cost-savings, since a single reporting system for reporting this information is less burdensome than multiple programs.

D. Alternatives Considered

Reporting under section 1128G of the Act is required by law, which limits the other policy options available. Section 1128G of the Act encourages transparency of financial relationships between physicians and teaching hospitals, and the pharmaceutical and device industry. Although, many of these relationships are beneficial, close relationships between manufacturers and prescribing providers can lead to conflicts of interests that may affect clinical decision-making. Increased transparency of these relationships tries to discourage inappropriate relationships, while maintaining the beneficial relationships. Public reporting and publication is the only statutorily permissible option for obtaining this transparency and achieving the intentions of this provision. In developing this final rule, we tried to minimize the burden on reporting entities by trying to simplify the reporting requirements as much as possible within the statutory requirements and in response to public comment.

The statute is prescriptive as to the types of information required to be reported, and the ways in which it is required to be reported; however wherever possible we tried to allow flexibility in the reporting requirements. For example, we note the following:

- We did not require the submission of an assumptions document for nature of payment categories, but allow applicable manufacturers and applicable GPOs to submit this voluntarily.
- The Secretary is allowed discretion to require the reporting of additional information, but we tried to use this discretion as sparingly as possible, in large part because of the strong desire expressed by stakeholders that we not expand reporting categories. For example, we considered asking applicable manufacturers and applicable GPOs to report the method of preferred communication and email address for physicians and teaching hospitals with which they have relationships, but based on the comments that this would be burdensome, we did not finalize it. In order to reduce the burden further, we could have not added any additional reporting categories (such as requiring State professional license number or NDC (if any)); however, we believe that all the additional reporting elements are necessary for the successful administration of the program and have tried to provide sufficient explanation of each decision.
- We limited the definition of covered drug, device, biological, and medical supply to reduce the number of entities meeting the definition of applicable manufacturer and applicable GPO. We proposed limiting covered drugs and biologicals to those that require a prescription to be dispensed and limiting covered devices (including medical supplies that are devices) to those that require premarket approval by or notification to the FDA. The comments strongly supported these limitations, so we have finalized them in the final rule.
- In the proposed rule, we defined ''common ownership'' as covering any ownership portion of two or more entities, but are finalizing an alternate interpretation that would limit the common ownership definition to circumstances where the same individual, individuals, entity, or entities own 5 percent or more of total ownership in two or more entities. Additionally, we provided further guidance on the phrase ''assistance and support'' in order to limit the number of entities under common ownership reporting. We could have employed a higher threshold of common ownership to further lower the burden; however, as explained in section II.B.1.a.(3). of this final rule, we believe that 5 percent is a standard threshold.
- In the proposed rule, we considered whether we should require that applicable manufacturers report another unique identifier, such as State license number, for physicians who are identified but do not have an NPI. Such an approach would provide additional information by which to cross-reference physicians who do not have an NPI, but the approach could also cause confusion if the additional information is not captured in a consistent manner. We received numerous comments on this provision and finalized the reporting of State professional license number for all physician covered recipients. The comments and rationale for this decision is discussed in section II.B.1.d.(1) of the preamble to this final rule.
- The Congress gave the Secretary authority to define a GPO and also specified that such organizations would include organizations that purchase covered drugs, devices, biologicals, and medical supplies, as well as organizations that arrange for or negotiate the purchase of covered drugs, devices, biologicals, and medical supplies. Therefore, we interpret the statute to encompass entities that purchase covered drugs, devices, biological, and medical supplies for resale or distribution to groups of individuals or entities. This would include physician owned distributors (PODs) of covered drugs, devices, biological, and medical supplies. We received numerous comments on this proposal and finalized the definition as proposed (see section II.B.2.a.(2). of the preamble of this final rule).
- We also finalized limitations that will reduce the reporting requirements for applicable manufacturers that only manufacture a few covered products. Applicable manufacturers with less than 10 percent of revenues from covered products do not need to report all payments or other transfers of value as proposed. This will greatly reduce the

[9] Information on the IOM recommendations may be found here: *http://www.iom.edu/Reports/2009/Conflict-of-Interest-in-Medical-Research-Education-and-Practice.aspx.*

burden of reporting for these entities, allowing them greater flexibility. We could have lowered the burden by including additional limitations to reporting by certain applicable manufacturers, but believe that the statute did not provide much flexibility to do so.

• We have finalized, as required by statute, a 45-day review period during which applicable manufacturers and GPOs, covered recipients, and physician owners or investors can review the data before it is made available to the public. In response to the comments, we have considered the best methods to administer this review, as well as any dispute resolution processes. We have finalized a dispute resolution system which will allow covered recipients and physician owners or investors to more easily review the information submitted on their behalf and a more streamline process to initiate disputes, as necessary.

Finally, it is important to evaluate and monitor if the changes reflected in this rule achieve the goal of improving transparency and accountability between health care providers and drug manufacturers. We will evaluate over time, and encourage others to evaluate, the effects of this rule on Medicaid enrollment, on Federal, State, and enrollee costs, and on health outcomes.

E. Accounting Statement

The Office of Management and Budget, in Circular A–4, requires an accounting Statement for rules with significant economic impacts. The table that follows shows the estimated costs annualized over a 10-year period. The estimated costs are $269 million in year 1 and $180 million in year 2. We assume that future outlay costs may be similar to those costs experienced in year 2. We envision that the number of financial relationships required to be reported will remain similar, so the cost of reporting the information will not change significantly.

TABLE 7—ACCOUNTING STATEMENT

Category	Primary estimate	Year dollars	Discount rate (percent)	Period covered
Annualized Monetized Costs	$192	2011	7	2013–2022
	190	2011	3	2013–2022
Benefits	Public reporting of the extent and nature of relationships between physicians, teaching hospitals, and industry manufacturers through increased transparency will permit patients to make better informed decisions when choosing health care professionals and making treatment decisions, and deter inappropriate financial relationships.			

F. Conclusions

Section 1128G of the Act requires applicable manufacturers to report annually to CMS certain payments or transfers of value provided to physicians or teaching hospitals. In addition, applicable GPOs are required to report annually certain physician ownership interests. We estimate that the impact of these reporting requirements will be about $269 million for the first year of reporting, and $180 million for the second year and annually thereafter. As we have indicated throughout, these are rough estimates and subject to considerable uncertainty. Better estimates might well be 25 percent higher or lower. Nonetheless, we believe that the public comment period offers an excellent opportunity for all stakeholders to consider alternatives and to present quantitative or qualitative information that will enable us to both improve the effectiveness and lower the costs of the final rule. Therefore, we solicited comment on the analysis and assumptions provided throughout this preamble and in the alternatives section of the regulatory impact analysis in particular.

Many of the comments received discuss our assumptions for the costs of collecting this information. Because this rule involves the collection of data, the vast majority of the financial impact is included in the collection of information requirements. Therefore earlier in the preamble of this final rule, we summarize and respond to the comments regarding our cost assumptions.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 402

Administrative practice and procedure, Medicaid, Medicare, Penalties.

42 CFR Part 403

Grant programs-health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 402—CIVIL MONEY PENALTIES, ASSESSMENTS, AND EXCLUSIONS

Subpart A—General Provisions

■ 1. The authority citation for part 402 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 402.1 is amended as follows:

■ A. In paragraph (c) introductory text, by removing the reference ''(c)(33)'' and adding the reference ''(c)(34)'' in its place.

■ B. Adding a new paragraph (c)(34).

The addition reads as follows:

§ 402.1 Basis and scope.

* * * * *

(c) * * *

(34) Section 1128G (b) (1) and (2)– Any applicable manufacturer or applicable group purchasing organization that fails to timely, accurately, or completely report a payment or other transfer of value or an ownership or investment interest to CMS, as required under part 403, subpart I, of this chapter.

* * * * *

■ 3. Section 402.105 is amended as follows:

■ A. In paragraph (a), by removing the reference to ''paragraphs (b) through (g)'' and adding the reference ''paragraphs (b) through (h)'' in its place.

■ B. Adding paragraphs (d)(5) and (h).

The additions read as follows:

§ 402.105 Amount of penalty.

* * * * *

(d) * * *

(5) CMS or OIG may impose a penalty of not more than $10,000 for each failure of an applicable manufacturer or an applicable group purchasing organization to report timely, accurately, or completely a payment or other transfer of value or an ownership or investment interest (§ 402.1(c)(34)). The total penalty imposed with respect to failures to report in an annual submission of information will not exceed $150,000.

* * * * *

(h) *$100,000.* CMS or OIG may impose a penalty of not more than $100,000 for each knowing failure of an applicable manufacturer or an applicable group purchasing organization to report timely, accurately or completely a payment or other transfer of value or an ownership or investment interest (§ 402.1(c)(34)). The total penalty imposed with respect to knowing failures to report in an annual submission of information will not exceed $1,000,000.

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 4. The authority citation for part 403 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 5. A new subpart I is added to part 403 to read as follows:

Subpart I—Transparency Reports and Reporting of Physician Ownership or Investment Interests

Sec.

Subpart I—Transparency Reports and Reporting of Physician Ownership or Investment Interests

§ 403.900 Purpose and scope.

The regulations in this subpart implement section 1128G of the Act. These regulations apply to applicable manufacturers and applicable group purchasing organizations and describe the requirements and procedures for applicable manufacturers to report payments or other transfers of value provided to covered recipients, as well as for applicable manufacturers and applicable group purchasing organizations to report ownership or investment interests held by physicians or immediate family members of physicians in such entities.

§ 403.902 Definitions.

For purposes of this subpart, the following definitions apply:

Applicable group purchasing organization means an entity that:

(1) Operates in the United States; and

(2) Purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, but not solely for use by the entity itself.

Applicable manufacturer means an entity that is operating in the United States and that falls within one of the following categories:

(1) An entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, but not if such covered drug, device, biological or medical supply is solely for use by or within the entity itself or by the entity's own patients. This definition does not include distributors or wholesalers (including, but not limited to, repackagers, relabelers, and kit assemblers) that do not hold title to any covered drug, device, biological or medical supply.

(2) An entity under common ownership with an entity in paragraph (1) of this definition, which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

Assistance and support means providing a service or services that are necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

Charitable contribution includes, but is not limited to, any payment or transfer of value made to an organization with tax-exempt status under the Internal Revenue Code of 1986, which is not provided in exchange for any goods, items or services.

Charity care means services provided by a covered recipient specifically for a patient who is unable to pay for such services or for whom payment would be a significant hardship, where the covered recipient neither receives, nor expects to receive, payment because of the patient's inability to pay.

Clinical investigation means any experiment involving one or more human subjects, or materials derived from human subjects, in which a drug, device, biological or medical supply is administered, dispensed or used.

Common ownership refers to circumstances where the same individual, individuals, entity, or entities directly or indirectly own 5 percent or more total ownership of two entities. This includes, but is not limited to, parent corporations, direct and indirect subsidiaries, and brother or sister corporations.

Covered device means any device for which payment is available under Title XVIII of the Act or under a State plan under Title XIX or XXI of the Act (or a waiver of such plan), either separately (such as through a fee schedule) or as part of a bundled payment (for example, under the hospital inpatient prospective payment system or the hospital outpatient prospective payment system) and which is of the type that, by law, requires premarket approval by or premarket notification to the Food and Drug Administration (FDA).

Covered drug, device, biological, or medical supply means any drug, device, biological, or medical supply for which payment is available under Title XVIII of the Act or under a State plan under Title XIX or XXI of the Act (or a waiver of such plan), either separately (such as through a fee schedule or formulary) or as part of a bundled payment (for example, under the hospital inpatient prospective payment system or the hospital outpatient prospective payment system) and which is of the type that in the case of a—

(1) Drug or biological, by law, requires a prescription to be dispensed; or

(2) Device (including a medical supply that is a device), by law, requires premarket approval by or premarket notification to the FDA.

Covered recipient means— (1) Any physician, except for a physician who is a bona fide employee of the applicable manufacturer that is reporting the payment; or

(2) A teaching hospital, which is any institution that received a payment under 1886(d)(5)(B), 1886(h), or 1886(s) of the Act during the last calendar year for which such information is available.

Employee means an individual who is considered to be ''employed by'' or an ''employee'' of an entity if the individual would be considered to be an employee of the entity under the usual common law rules applicable in determining the employer-employee relationship (as applied for purposes of

section 3121(d)(2) of the Internal Revenue Code of 1986).

Immediate family member means any of the following:

(1) Spouse.

(2) Natural or adoptive parent, child, or sibling.

(3) Stepparent, stepchild, stepbrother, or stepsister.

(4) Father-, mother-, daughter-, son-, brother-, or sister-in-law.

(5) Grandparent or grandchild.

(6) Spouse of a grandparent or grandchild.

Indirect payments or other transfers of value refer to payments or other transfers of value made by an applicable manufacturer (or an applicable group purchasing organization) to a covered recipient (or a physician owner or investor) through a third party, where the applicable manufacturer (or applicable group purchasing organization) requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient(s) (or a physician owner or investor).

Know, knowing, or knowingly—(1) Means that a person, with respect to information—

(i) Has actual knowledge of the information;

(ii) Acts in deliberate ignorance of the truth or falsity of the information; or

(iii) Acts in reckless disregard of the truth or falsity of the information; and

(2) Requires no proof of a specific intent to defraud.

NPPES stands for the National Plan & Provider Enumeration System.

Operating in the United States means that an entity—

(1) Has a physical location within the United States or in a territory, possession, or commonwealth of the United States; or

(2) Otherwise conducts activities within the United States or in a territory, possession, or commonwealth of the United States, either directly or through a legally-authorized agent.

Ownership or investment interest—(1) Includes, but is not limited to the following:

(i) Stock, stock option(s) (other than those received as compensation, until they are exercised).

(ii) Partnership share(s);

(iii) Limited liability company membership(s).

(iv) Loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue.

(2) May be direct or indirect and through debt, equity or other means.

(3) *Exceptions.* The following are not ownership or investment interests for the purposes of this section:

(i) An ownership or investment interest in a publicly traded security or mutual fund, as described in section 1877(c) of the Act.

(ii) An interest in an applicable manufacturer or applicable group purchasing organization that arises from a retirement plan offered by the applicable manufacturer or applicable group purchasing organization to the physician (or a member of his or her immediate family) through the physician's (or immediate family member's) employment with that applicable manufacturer or applicable group purchasing organization.

(iii) Stock options and convertible securities received as compensation, until the stock options are exercised or the convertible securities are converted to equity.

(iv) An unsecured loan subordinated to a credit facility.

(v) An ownership or investment interest if an applicable manufacturer or applicable group purchasing organization did not know, as defined in this section, about such ownership or investment interest.

Payment or other transfer of value means a transfer of anything of value.

Physician has the same meaning given that term in section 1861(r) of the Act.

Related to a covered drug, device, biological, or medical supply means that a payment or other transfer of value is made in reference to or in connection with one or more covered drugs, devices, biologicals, or medical supplies.

Research includes a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research and product development.

Third party means another individual or entity, regardless of whether such individual or entity is operating in the United States.

§ 403.904 Reports of payments or other transfers of value to covered recipients.

(a) *General rule.* (1) Direct and indirect payments or other transfers of value provided by an applicable manufacturer to a covered recipient during the preceding calendar year, and direct and indirect payments or other transfers of value provided to a third party at the request of or designated by the applicable manufacturer on behalf of a covered recipient during the preceding calendar year, must be reported by the applicable manufacturer to CMS on an annual basis.

(2) For CY 2013, only payments or other transfers of value made on or after August 1, 2013 must be reported to CMS.

(b) *Limitations.* Certain limitations on reporting apply in the following circumstances:

(1) Applicable manufacturers for whom total (gross) revenues from covered drugs, devices, biologicals, or medical supplies constituted less than 10 percent of total (gross) revenue during the fiscal year preceding the reporting year are only required to report payments or other transfers of value that are related to one or more covered drugs, devices, biologicals or medical supplies.

(2) Applicable manufacturers under paragraph (2) of the definition in § 403.902 are only required to report payments or other transfers of value that are related to a covered drug, device, biological, or medical supply for which they provided assistance or support to an applicable manufacturer under paragraph (1) of the definition.

(3) Applicable manufacturers under either paragraph (1) or (2) of the definition in § 403.902 that have separate operating divisions that do not manufacture any covered drugs, devices, biologicals, or medical supplies (for example, animal health divisions) are only required to report payments to covered recipients related to the activities of these separate divisions if those payments or other transfers of value are related to a covered drug, device, biological, or medical supply. This includes reporting of payments or other transfers of value that are related to covered drugs, devices, biologicals, or medical supplies made by applicable manufacturers to covered recipients through these operating divisions.

(4) Applicable manufacturers that do not manufacture a covered drug, device, biological, or medical supply except when under a written agreement to manufacture the covered drug, device, biological, or medical supply for another entity, do not hold the FDA approval, licensure, or clearance for the covered drug, device, biological, or medical supply, and are not involved in the sale, marketing, or distribution of the product, are only required to report payments or other transfers of value that are related to one or more covered drugs, devices, biologicals, or medical supplies.

(c) *Required information to report.* A report must contain all of the following information for each payment or other transfer of value:

(1) *Name of the covered recipient.* For physician covered recipients, the name must be as listed in the National Plan & Provider Enumeration System (if applicable) and include first and last name, middle initial, and suffix (for all that apply).

(2) *Address of the covered recipient.* Primary business address of the covered recipient, including all the following:

(i) Street address.

(ii) Suite or office number (if applicable).

(iii) City.

(iv) State.

(v) ZIP code.

(3) *Identifiers for physician covered recipients.* In the case of a covered recipient who is a physician, the following identifiers:

(i) The specialty.

(ii) National Provider Identifier (if applicable and as listed in the NPPES). If a National Provider Identifier cannot be identified for a physician, the field may be left blank, indicating that the applicable manufacturer could not find one.

(iii) State professional license number(s) (for at least one State where the physician maintains a license), and the State(s) in which the license is held.

(4) *Amount of payment or other transfer of value.* A payment or other transfer of value made to a group of covered recipients should be distributed appropriately among the individual covered recipients who requested the payment, on whose behalf the payment was made, or who are intended to benefit from the payment or other transfer of value.

(5) *Date of payment or transfer of value.* The date of each payment or other transfer of value.

(i) For payments or other transfers of value made over multiple dates (rather than as a lump sum), applicable manufacturers may choose whether to report each payment or other transfer of value as separate line item using the dates the payments or other transfers of value were each made, or as a single line item for the total payment or other transfer of value using the first payment date as the reported date.

(ii) For small payments or other transfers of value reported as a single line item, applicable manufacturers must report the date that the first bundled small payment or other transfer of value was provided to the covered recipient.

(6) *Form of payment or transfer of value.* The form of each payment or other transfer of value, as described in paragraph (d) of this section.

(7) *Nature of payment or transfer of value.* The nature of each payment or other transfer of value, as described in paragraph (e) of this section.

(8) *Related covered drug, device, biological or medical supply.* The name(s) of the related covered drugs, devices, biologicals, or medical supplies, unless the payment or other transfer of value is not related to a particular covered drug, device, biological or medical supply. Applicable manufacturers may report up to five covered drugs, devices, biologicals or medical supplies related to each payment or other transfer of value. If the payment or other transfer of value was related to more than five covered drugs, devices, biologicals, or medical supplies, the applicable manufacturer should report the five covered drugs, devices, biologicals, or medical supplies that were most closely related to the payment or other transfer of value.

(i) For drugs and biologicals, applicable manufacturers must report the name under which the drug or biological is or was marketed and the relevant National Drug Code(s), if any. If the marketed name has not yet been selected, the applicable manufacturer must indicate the name registered on clinicaltrials.gov.

(ii) For devices and medical supplies, applicable manufacturers must report at least one of the following:

(A) The name under which the device or medical supply is or was marketed.

(B) The therapeutic area or product category for the device or medical supply.

(iii) If the payment or other transfer of value is not related to a covered drug, device, biological or medical supply, but is related to a specific non-covered product, applicable manufacturers must indicate ''non-covered product.''

(iv) If the payment or other transfer of value is not related to any drug, device, biological, or medical supply (covered or not), applicable manufacturers must indicate ''none.''

(v) If the payment or other transfer of value is related to at least one covered drug, device, biological, and medical supply and at least one non-covered drug, device, biological, or medical supply, applicable manufacturers must report the name(s) of the covered drug, device, biological or medical supply (as required by paragraphs (c)(8)(i) and (ii) of this section) and may indicate ''non-covered products'' in addition.

(9) *Eligibility for delayed publication.* Applicable manufacturers must indicate whether a payment or other transfer of value is eligible for delayed publication, as described in § 403.910.

(10) *Payments to third parties.* (i) If the payment or other transfer of value was provided to a third party at the request of or designated on behalf of a covered recipient, the payment or transfer of value must be reported in the name of that covered recipient.

(ii) If the payment or other transfer of value was provided to a third party at the request of or designated on behalf of a covered recipient, the name of the entity that received the payment or other transfer of value (if made to an entity) or indicate ''individual'' (if made to an individual). If a covered recipient performed a service, but neither accepted the offered payment or other transfer of value nor requested that it be made to a third party, the applicable manufacturer is not required to report the offered payment or other transfer of value unless the applicable manufacturer nonetheless provided it to a third party and designated such payment or other transfer of value as having been provided on behalf of the covered recipient.

(11) *Payments or transfers of value to physician owners or investors.* Must indicate whether the payment or other transfer of value was provided to a physician or the immediate family of the physician who holds an ownership or investment interest (as defined § 403.902) in the applicable manufacturer.

(12) *Additional information or context for payment or transfer of value.* May provide a statement with additional context for the payment or other transfer of value.

(d) *Reporting the form of payment or other transfer of value.* An applicable manufacturer must report each payment or transfer of value, or separable part of that payment or transfer of value, as taking one of the following forms of payment that best describes the form of the payment or other transfer of value, or separable part of that payment or other transfer of value.

(1) Cash or cash equivalent.

(2) In-kind items or services.

(3) Stock, stock option, or any other ownership interest.

(4) Dividend, profit or other return on investment.

(e) *Reporting the nature of the payment or other transfer of value.* (1) *General rule.* The categories describing the nature of a payment or other transfer of value are mutually exclusive for the purposes of reporting under subpart I of this part.

(2) *Rules for categorizing natures of payment.* An applicable manufacturer must categorize each payment or other transfer of value, or separable part of that payment or transfer of value, with one of the categories listed in paragraphs (e)(2)(i) through (xvii) of this

section, using the designation that best describes the nature of the payment or other transfer of value, or separable part of that payment or other transfer of value. If a payment or other transfer of value could reasonably be considered as falling within more than one category, the applicable manufacturer should select one category that it deems to most accurately describe the nature of the payment or transfer of value.

(i) Consulting fee.

(ii) Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program.

(iii) Honoraria.

(iv) Gift.

(v) Entertainment.

(vi) Food and beverage.

(vii) Travel and lodging (including the specified destinations).

(viii) Education.

(ix) Research.

(x) Charitable contribution.

(xii) Royalty or license.

(xiii) Current or prospective ownership or investment interest.

(xiv) Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program.

(xv) Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program.

(xvi) Grant.

(xvii) Space rental or facility fees (teaching hospital only).

(f) *Special rules for research payments.* All payments or other transfers of value made in connection with an activity that meets the definition of research in this section and that are subject to a written agreement, a research protocol, or both, must be reported under these special rules.

(1) Research-related payments or other transfers of value to covered recipients (either physicians or teaching hospitals), including research-related payments or other transfers of value made indirectly to a covered recipient through a third party, must be reported to CMS separately from other payments or transfers of value, and must include the following information (in lieu of the information required by § 403.904(c)):

(i) Name of the research institution, individual or entity receiving the payment or other transfer of value.

(A) If paid to a physician covered recipient, all of the following must be provided:

(*1*) The physician's name as listed in the NPPES (if applicable).

(*2*) National Provider Identifier.

(*3*) State professional license number(s) (for at least one State where the physician maintains a license) and State(s) in which the license is held.

(*4*) Specialty.

(*5*) Primary business address of the physician(s).

(B) If paid to a teaching hospital covered recipient, list the name and primary business address of teaching hospital.

(C) If paid to a non-covered recipient (such as a non-teaching hospital or clinic), list the name and primary business address of the entity.

(ii) Total amount of the research payment, including all research-related costs for activities outlined in a written agreement, research protocol, or both.

(iii) Name of the research study.

(iv) Name(s) of any related covered drugs, devices, biologicals, or medical supplies (subject to the requirements specified in paragraph (c)(8) of this section) and for drugs and biologicals, the relevant National Drug Code(s), if any.

(v) Information about each physician covered recipient principal investigator (if applicable) set forth in paragraph (f)(1)(i)(A) of this section.

(vi) Contextual information for research (optional).

(vii) ClinicalTrials.gov identifier (optional).

(2) For pre-clinical studies (before any human studies have begun), only report the following information:

(i) Research entity name (as required in paragraph (f)(1)(i) of this section).

(ii) Total amount of payment (as required in paragraph (f)(1)(ii) of this section).

(ii) Principal investigator(s) (as required in paragraph (f)(1)(v) of this section).

(g) *Special rules for payments or other transfers of value related to continuing education programs.* (1) Payments or other transfers of value provided as compensation for speaking at a continuing education program are not required to be reported, if all of the following conditions are met:

(i) The event at which the covered recipient is speaking meets the accreditation or certification requirements and standards for continuing education of one of the following:

(A) The Accreditation Council for Continuing Medical Education.

(B) The American Academy of Family Physicians.

(C) The American Dental Association's Continuing Education Recognition Program.

(D) The American Medical Association.

(E) The American Osteopathic Association.

(ii) The applicable manufacturer does not pay the covered recipient speaker directly.

(iii) The applicable manufacturer does not select the covered recipient speaker or provide the third party (such as a continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers for the continuing education program.

(2) Payments or other transfers of value that do not meet all of the requirements in paragraph (g)(1) must be reported as required by this section.

(i) Payments or other transfers of value that meet the requirements in paragraph (g)(1)(i) of this section, but not also (g)(1)(ii) or (g)(1)(iii) of this section or both, must be reported under the nature of payment category ''Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program.''

(ii) Payments or other transfers of value that do not meet the requirements in paragraph (g)(1)(i) of this section should be reported under the nature of payment category ''Compensation for serving as a faculty or as a speaker for a unaccredited and non-certified continuing education program.''

(iii) Payments or other transfers of value for speaking engagements not related to medical education should be reported under the nature of payment category ''Compensation for services other than consulting, including serving as a speaker at an event other than a continuing education program.''

(h) *Special rules for reporting food and beverage.* (1) When allocating the cost of food and beverage among covered recipients in a group setting where the cost of each individual covered recipient's meal is not separately identifiable, such as a platter provided to physicians in a group practice setting, applicable manufacturers must calculate the value per person by dividing the entire cost of the food or beverage by the total number of individuals who partook in the meal (including both covered recipients and non-covered recipients, such as office staff). The per person value of the meal must be reported as a payment or other transfer of value only for covered recipients who actually partook in the food or beverage.

(2) Applicable manufacturers are not required to report or track buffet meals, snacks, soft drinks, or coffee made generally available to all participants of a large-scale conference or similar large-scale event.

(i) *Exclusions from reporting.* The following are excluded from the

reporting requirements specified in this section:

(1) Indirect payments or other transfers of value (as defined in § 403.902), where the applicable manufacturer is unaware of the identity of the covered recipient. An applicable manufacturer is unaware of the identity of a covered recipient if the applicable manufacturer does not know (as defined in § 403.902) the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year.

(2)(i) For CY 2013, payments or other transfers of value less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds $100 in a calendar year.

(ii) For CY 2014 and subsequent calendar years, to determine if transfers of value are excluded under this section, the dollar amounts specified in paragraph (i)(2)(i) of this section must be increased by the same percentage as the percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year. CMS will publish the values for the next reporting year 90 days before the beginning of the reporting year.

(iii) Payments or other transfers of value of less than $10 in CY 2013 (or less than the amount described in paragraph (i)(2)(ii) of this section for CY 2014 and subsequent calendar years) provided at large-scale conferences and similar large-scale events, as well as events open to the public, do not need to be reported nor included for purposes of the $100 aggregate threshold in CY 2013 (or the aggregate threshold calculated in accordance paragraph (i)(2)(ii) of this section for CY 2014 and subsequent calendar years), even if the aggregate total for a covered recipient exceeds the aggregate threshold for the calendar year.

(iv) When reporting payments or other transfers of value under the $10 threshold for CY 2013 (or under the amount described in paragraph (i)(2)(ii) of this section for CY 2014 and subsequent calendar years) for covered recipients that exceed the aggregate threshold for the reporting year, applicable manufacturers may (but are not required to) report all small payments to a particular covered recipient that fall within the same nature of payment category as a single payment or other transfer of value.

(3) Product samples, including coupons and vouchers that can be used by a patient to obtain samples, which are not intended to be sold and are intended for patient use.

(4) Educational materials and items that directly benefit patients or are intended to be used by or with patients, including the value of an applicable manufacturer's services to educate patients regarding a covered drug, device, biological, or medical supply.

(5) The loan of a covered device or a device under development, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 days or a quantity of 90 days of average daily use, to permit evaluation of the device or medical supply by the covered recipient.

(6) Items or services provided under a contractual warranty (including service or maintenance agreements), whether or not the warranty period has expired, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.

(7) A transfer of anything of value to a physician covered recipient when the covered recipient is a patient, research subject or participant in data collection for research, and not acting in the professional capacity of a covered recipient.

(8) Discounts, including rebates.

(9) In-kind items used for the provision of charity care.

(10) A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund.

(11) In the case of an applicable manufacturer who offers a self-insured plan or directly reimburses for healthcare expenses, payments for the provision of health care to employees and their families.

(12) In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of the licensed non-medical professional.

(13) In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to an administrative proceeding, legal defense, prosecution, or settlement or judgment of a civil or criminal action and arbitration.

(14) A payment or transfer of value to a covered recipient if the payment or transfer of value is made solely in the context of a personal, non-business-related relationship.

§ 403.906 Reports of physician ownership and investment interests.

(a) *General rule.* (1) Each applicable manufacturer and applicable group purchasing organization must report to CMS on an annual basis all ownership and investment interests in the applicable manufacturer or applicable group purchasing organization that were held by a physician or an immediate family member of a physician during the preceding calendar year.

(2) For CY 2013, only ownership or investment interests held on or after August 1, 2013 must be reported to CMS.

(b) *Identifying information.* Reports on physician ownership and investment interests must include the following identifying information:

(1) Name of the physician (as listed in the National Plan & Provider Enumeration System (if applicable), including first and last name, middle initial, and suffix (for all that apply), and an indication of whether the ownership or investment interest was held by the physician or an immediate family member of the physician.

(2) Primary business address of the physician, including the following:

(i) Street address.

(ii) Suite or office number (if applicable).

(iii) City.

(iv) State.

(v) ZIP code.

(3) The following information for the physician (regardless of whether the ownership or investment interest is held by an immediate family member of the physician):

(i) The specialty.

(ii) National Provider Identifier (if applicable and as listed in NPPES).

(iii) State professional license number(s) (for at least one State where the physician maintains a license), and the State(s) in which the license is held.

(4) Dollar amount invested by each physician or immediate family member of the physician.

(5) Value and terms of each ownership or investment interest.

(6) Direct and indirect payments or other transfers of value provided to a physician holding an ownership or investment interest, and direct and indirect payments or other transfers of value provided to a third party at the request of or designated by the applicable manufacturer or applicable group purchasing organization on behalf of a physician owner or investor, must be reported by the applicable manufacturer or applicable group purchasing organization in accordance with the requirements for reporting payments or other transfers of value in

§ 403.904(c) through (i). The terms ''applicable manufacturer and applicable group purchasing organization'' must be substituted for ''applicable manufacturer,'' and ''physician owner or investor'' must be substituted for ''covered recipient'' in each place they appear.

§ 403.908 Procedures for electronic submission of reports.

(a) *File format.* Reports required under this subpart must be electronically submitted to CMS by March 31, 2014, and by the 90th day of each subsequent calendar year.

(b) *General rules.* (1) If an applicable manufacturer made no reportable payments or transfers of value in the previous calendar year, nor had any reportable ownership or investment interests held by a physician or a physician's immediate family member (as defined in § 403.902) during the previous calendar year, the applicable manufacturer is not required to file a report.

(2) If an applicable group purchasing organization had no reportable ownership or investment interests held by a physician or physician's immediate family member during the previous calendar year, the applicable group purchasing organization is not required to file a report.

(c) *Registration.* (1) Applicable manufacturers that have reportable payments or other transfers of value, ownership or investment interests, or both, are required to report under this subpart and must register with CMS within 90 days of the end of the calendar year for which a report is required.

(2) Applicable group purchasing organizations that have reportable ownership or investment interests are required to report under this subpart and must register with CMS within 90 days of the end of the calendar year for which a report is required.

(3) During registration, applicable manufacturers and applicable group purchasing organizations must name two points of contact with appropriate contact information.

(d) *Other rules.* (1) *Consolidated reports.* (i) An applicable manufacturer under paragraph (1) of the definition that is under common ownership with separate entities that are also applicable manufacturers under paragraph (1) of the definition may, but is not required to, file a consolidated report of all the payments or other transfers of value to covered recipients, and physician ownership or investment interests, for all of the entities.

(ii) An applicable manufacturer under paragraph (1) of the definition of applicable manufacturer and an entity (or entities) under common ownership with the applicable manufacturer under paragraph (2) of the definition of applicable manufacturer may, but are not required to, file a consolidated report of all the payments or other transfers of value to covered recipients, and physician ownership or investment interests.

(iii) If multiple applicable manufacturers (under paragraph (1) or (2) of the definition or both paragraphs of the definition) submit a consolidated report, the report must provide the names of each applicable manufacturer and entity (or entities) under common ownership that the report covers, and the report must identify the specific entity that provided each payment.

(iv) A single payment or other transfer of value reported in a consolidated report must only be reported once by one applicable manufacturer.

(v) The applicable manufacturer submitting a consolidated report on behalf of itself and other applicable manufacturers under common ownership, as permitted under this paragraph, is liable for civil monetary penalties imposed on each of the applicable manufacturers whose reportable payments or other transfers of value were included in the consolidated report, up to the annual maximum amount specified in § 403.912(c) for each individual applicable manufacturer included in the report.

(2) *Joint ventures.* If a payment or other transfer of value is provided in accordance with a joint venture or other cooperative agreement between two or more applicable manufacturers, the payment or other transfer of value must be reported—

(i) In the name of the applicable manufacturer that actually furnished the payment or other transfer of value to the covered recipient, unless the terms of a written agreement between the applicable manufacturers specifically require otherwise, so long as the agreement requires that all payments or other transfers of value in accordance with the arrangement are reported by one of the applicable manufacturers; and

(ii) Only once by one applicable manufacturer.

(e) *Attestation.* Each report, including any subsequent corrections to a filed report, must include an attestation by the Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer of the applicable manufacturer or applicable group purchasing organization that the information reported is timely, accurate, and complete to the best of his or her knowledge and belief. For applicable manufacturers choosing to submit a consolidated report in accordance with paragraph (d)(1) of this section, the applicable manufacturer submitting the consolidated report must attest on behalf of itself, in addition to each of the other applicable manufacturers included in the consolidated report.

(f) *Assumptions document.* Applicable manufacturers and applicable group purchasing organizations may submit an assumptions document, explaining the reasonable assumptions made and methodologies used when reporting payments or other transfers of value, or ownership or investment interests. The assumptions documents will not be made available to covered recipients, physician owners or investors, or the public.

(g) *45-day review period for review and error correction.* (1) *General rule.* Applicable manufacturers, applicable group purchasing organizations, covered recipients, and physician owners or investors must have an opportunity to review and submit corrections to the information submitted for a period of not less than 45-days before CMS makes the information available to the public. In no case may this 45-day period for review and submission of corrections prevent the information from being made available to the public.

(2) *Notification.* CMS notifies the applicable manufacturers, applicable group purchasing organizations, covered recipients, and physician owners or investors when the reported information is ready for review.

(i) Applicable manufacturers and applicable group purchasing organizations are notified through the points of contact they identified during registration.

(ii) Physicians and teaching hospitals—

(A) Are notified using an online posting and notifications on CMS's listserves.

(B) May also register with CMS to receive notification about the review processes.

(iii) The 45-day review period begins on the date specified in the online notification.

(3) *Process.* (i) An applicable manufacturer, applicable group purchasing organization, covered recipient or a physician owner or investor may log into a secure Web site to view only the information reported specifically about itself.

(ii) Covered recipients and physician owners or investors are able to review

data submitted about them for the previous reporting year.

(iii) If the applicable manufacturer, applicable group purchasing organization, covered recipient, or physician owner or investor agrees with the information reported, the applicable manufacturer, applicable group purchasing organization, covered recipient, or physician owner or investor may electronically certify that the information reported is accurate.

(iv) If a covered recipient or physician owner or investor disagrees with the information reported, the covered recipient or physician owner or investor can initiate a dispute, which is sent to the appropriate applicable manufacturer or applicable group purchasing organization to be resolved between the parties.

(v) Covered recipients and physician owners or investors may initiate disputes at any time after the 45-day period begins, but before the end of the calendar year, but any changes resulting from disputes initiated outside the 45-day period, may not be made until the next time the data is refreshed.

(4) *Data disputes.* (i) In order to be corrected prior to the publication of the data, applicable manufacturers and applicable group purchasing organizations must notify CMS of resolved disputes and changes to the information submitted by no later than 15 days after the end of the 45-day period (that is, 60 days after the 45-day review period begins).

(ii) Disputes which are not resolved by 15 days after the end of the review and correction period, may still be resolved, but any changes resulting from the disputes may be made until the next time the data is refreshed.

(iii) If the dispute is not resolved by 15 days after the end of the 45-day review and correction period, CMS publicly reports and aggregates the applicable manufacturer's or applicable group purchasing organization's version of the payment or other transfer of value, or ownership or investment interest data, but marks the payment or other transfer of value or ownership or investment interest as disputed.

(h) *Errors or omissions.* (1) If an applicable manufacturer or applicable group purchasing organization discovers an error or omission in its annual report, it must submit corrected information to CMS immediately upon confirmation of the error or omission.

(2) Upon receipt, CMS notifies the affected covered recipient or physician owner or investor that the additional information has been submitted and is available for review. CMS updates the Web site at least once annually with corrected information.

§ 403.910 Delayed publication for payments made under product research or development agreements and clinical investigations.

(a) *General rule.* Certain research payments or other transfers of value made to a covered recipient by an applicable manufacturer under a product research or development agreement may be delayed from publication on the Web site. Publication of a payment or other transfer of value is delayed when made in connection with the following instances:

(1) Research on or development of a new drug, device, biological, or medical supply, or a new application of an existing drug, device, biological, or medical supply.

(2) Clinical investigations regarding a new drug, device, biological, or medical supply.

(b) *Research or development agreement.* The research or development agreement must include a written agreement, a research protocol, or both between the applicable manufacturer and covered recipient.

(c) *Date of publication.* Payments or other transfers of value eligible for delayed publication must be reported to CMS (in the manner required in § 403.904(f)) on the first reporting date following the year in which they occur, but CMS does not publicly post the payment until the first annual publication date after the earlier of the following:

(1) The date of the approval, licensure or clearance of the covered drug, device, biological, or medical supply by FDA.

(2) Four calendar years after the date the payment or other transfer of value was made.

(d) *Notification of delayed publication.* (1) An applicable manufacturer must indicate on its research report to CMS whether a payment or other transfer of value is eligible for a delay in publication. The absence of this indication in the report will result in CMS posting all payments publicly in the first year of public reporting.

(2) An applicable manufacturer must continue to indicate annually in its report that FDA approval, licensure, or clearance of the new drug, device, biological or medical supply to which the payment or other transfer of value is related, is pending.

(3) An applicable manufacturer must notify CMS during subsequent annual submissions, if the new drug, device, biological or medical supply, to which the payment is related (or the new application of the existing drug, device, biological, or medical supply), is approved by the FDA.

(4) Failure to notify CMS when FDA approval occurs may be considered failure to report, and the applicable manufacturer may be subject to civil monetary penalties.

(5) If, after 4 years from the date of a payment first appearing in a report to CMS, there is an indication in a report that the payment is subject to delayed reporting, it is reported regardless of the indication.

(e) *Confidentiality.* Information submitted and eligible for delayed publication is considered confidential and will not be subject to disclosure under 5 U.S.C. 552, or any similar Federal, State, or local law, until on or after the date on which the information made available to the public as required in this section.

§ 403.912 Penalties for failure to report.

(a) *Failure to report.* (1) Any applicable manufacturer or applicable group purchasing organization that fails to timely, accurately or completely report the information required in accordance with the rules established under this subpart is subject to a civil monetary penalty of not less than $1,000, but not more than $10,000, for each payment or other transfer of value or ownership or investment interest not reported timely, accurately, or completely.

(2) The total amount of civil monetary penalties imposed on each applicable manufacturer or applicable group purchasing organization (regardless of whether the applicable manufacturer was a part of a consolidated report) with respect to failures to report in an annual submission of information will not exceed $150,000.

(b) *Knowing failure to report.* (1) Any applicable manufacturer or applicable group purchasing organization that knowingly fails to timely, accurately or completely report the information required in accordance with the rules established under this subpart is subject to a civil monetary penalty of not less than $10,000, but not more than $100,000, for each payment or other transfer of value or ownership or investment interest not reported timely, accurately, or completely.

(2) The total amount of civil monetary penalties imposed on each applicable manufacturer or group purchasing organization (regardless of whether the applicable manufacturer was a part of a consolidated report) with respect to knowing failures to report in an annual submission of information will not exceed $1,000,000.

(c) *Total annual civil monetary penalties.* The amount of civil monetary penalties imposed on each applicable manufacturer or applicable group purchasing organization under paragraphs (a)(1) and (b)(1) of this section are—

(1) Aggregated separately;

(2) Subject to separate aggregate totals under paragraphs (a)(2) and (b)(2) of this section, with a maximum combined annual total of $1,150,000.

(d) *Determinations regarding the amount of civil monetary penalties.* In determining the amount of the civil monetary penalty, factors to be considered include, but are not limited to, the following:

(1) The length of time the applicable manufacturer or applicable group purchasing organization failed to report, including the length of time the applicable manufacturer or applicable group purchasing organization knew of the payment or other transfer of value, or ownership or investment interest.

(2) Amount of the payment the applicable manufacturer or applicable group purchasing organization failed to report.

(3) Level of culpability.

(4) Nature and amount of information reported in error.

(5) Degree of diligence exercised in correcting information reported in error.

(e) *Record retention and audits.* (1) *Maintenance of records.* (i) Applicable manufacturers and applicable group purchasing organizations must maintain all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, and inspection of the applicable manufacturer's or applicable group purchasing organization's compliance with the requirement to timely, accurately or completely submit information in accordance with the rules established under this subpart.

(ii) The items described in paragraph (e)(1)(i) of this section must be maintained for a period of at least 5 years from the date the payment or other transfer of value, or ownership or investment interest is published publicly on the Web site.

(2) *Audit.* HHS, CMS, OIG or their designees may audit, inspect, investigate and evaluate any books, contracts, records, documents, and other evidence of applicable manufacturers and applicable group purchasing organizations that pertain to their compliance with the requirement to timely, accurately or completely submit information in accordance with the rules established under this subpart.

(3) The requirements in this subpart are in addition to, and do not limit, any other applicable requirements that may obligate applicable manufacturers or applicable group purchasing organizations to retain and allow access to records.

(f) *Use of funds.* Funds collected by the Secretary as a result of the imposition of a civil monetary penalty under this section must be used to carry out the operation of this subpart.

(g) *Notice, hearings, appeals, and collection.* Civil monetary penalties imposed under this section are subject to the provisions set forth in subparts A and B of part 402 of this chapter, including those pertaining to notice, opportunity for a hearing, appeals procedures, and collection of penalties.

§ 403.914 Preemption of State laws.

(a) *General rule.* In the case of a payment or other transfer of value provided by an applicable manufacturer to a covered recipient, this subpart preempts any statute or regulation of a State or political subdivision of a State that requires an applicable manufacturer to disclose or report, in any format, the type of information regarding the payment or other transfer of value required to be reported under this subpart.

(b) *Information collected for public health purposes.* (1) Information required to be reported to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes must still be reported to appropriate Federal, State, or local governmental agencies, regardless of whether the same information is required to be reported under this subpart.

(2) Governmental agencies include, but are not limited to, the following:

(i) Agencies that are charged with preventing or controlling disease, injury, disability.

(ii) Agencies that conduct oversight activities authorized by law, including audits, investigations, inspections, licensure or disciplinary actions, or other activities necessary for oversight of the health care system.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: July 2, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: *January 23, 2013.*

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2013–02572 Filed 2–1–13; 4:15 pm]

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Part III

Department of Agriculture

Food and Nutrition Service

7 CFR Parts 210 and 220

National School Lunch Program and School Breakfast Program: Nutrition Standards for All Foods Sold in School as Required by the Healthy, Hunger-Free Kids Act of 2010; Proposed Rule

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Parts 210 and 220

[FNS–2011–0019]

RIN 0584–AE09

National School Lunch Program and School Breakfast Program: Nutrition Standards for All Foods Sold in School as Required by the Healthy, Hunger-Free Kids Act of 2010

AGENCY: Food and Nutrition Service, USDA.

ACTION: Proposed rule.

SUMMARY: This rule proposes to amend the National School Lunch Program and School Breakfast Program regulations consistent with amendments made in the Healthy, Hunger-Free Kids Act of 2010 (HHFKA). The HHFKA requires that the Secretary promulgate proposed regulations to establish nutrition standards for foods sold in schools other than those foods provided under the Child Nutrition Act of 1966 (CNA) and the Richard B. Russell National School Lunch Act (NSLA). The HHFKA amends the CNA, requiring that such standards shall be consistent with the most recent Dietary Guidelines for Americans and that the Secretary shall consider authoritative scientific recommendations for nutrition standards; existing school nutrition standards, including voluntary standards for beverages and snack foods; current State and local standards; the practical application of the nutrition standards; and special exemptions for infrequent school-sponsored fundraisers (other than fundraising through vending machines, school stores, snack bars, a la carte sales and any other exclusions determined by the Secretary). The HHFKA also amended the NSLA to require that schools participating in the National School Lunch Program make potable water available to children at no charge in the place where lunches are served during the meal service. These proposed changes are intended to improve the health and well-being of the Nation's children, increase consumption of healthful foods during the school day and create an environment that reinforces the development of healthy eating habits.

DATES: Online comments submitted through the Federal eRulemaking Portal on this proposed rule must be received on or before April 9, 2013. Mailed comments on this rule must be postmarked on or before April 9, 2013.

Comments on Paperwork Reduction Act requirements: Comments on the information collection requirements associated with this rule must be received by April 9, 2013.

ADDRESSES: The Food and Nutrition Service (FNS) invites interested persons to submit comments on this proposed rule. Comments may be submitted by either of the following methods:

- *Federal eRulemaking Portal:* Comments on the provisions in this rule must be received on or before April 9, 2013 to be assured of consideration. Go to *http://www.regulations.gov,* select ''Food and Nutrition Service'' from the agency drop-down menu, and click ''Submit.'' In the Docket ID column of the search results select ''FNS–2011–0019'' to submit or view public comments and to view supporting and related materials available electronically. Information on using Regulations.gov, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''User Tips'' link.
- *By Mail:* Mailed comments on the provisions in this rule must be postmarked on or before April 9, 2013 to be assured of consideration and should be sent to Julie Brewer, Chief, Policy and Program Development Branch, Child Nutrition Division, Food and Nutrition Service, P.O. Box 66874, Saint Louis, MO 63166.

All submissions received in response to this proposed rule will be included in the record and will be available to the public. Please be advised that the substance of the comments and the identity of the individuals or entities submitting comments will be subject to public disclosure. FNS will also make the comments publicly available by posting a copy of all comments on *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Julie Brewer, Chief, Policy and Program Development Branch, Child Nutrition Division, Food and Nutrition Service, 3101 Park Center Drive, Alexandria, Virginia 22302, or by telephone at (703) 305–2590.

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of the Regulatory Action

This proposed rule sets forth provisions to implement sections 203 and 208 of Public Law 111–296, the Healthy, Hunger-Free Kids Act of 2010 (HHFKA) for schools that participate in the National School Lunch Program (NSLP) and the School Breakfast Program (SBP). This rule proposes to amend the NSLP and SBP regulations consistent with amendments made in the HHFKA. The HHFKA requires the Secretary to promulgate proposed regulations to establish nutrition standards for foods sold in schools other than those foods provided under the Child Nutrition Act of 1966 (CNA) and the Richard B. Russell National School Lunch Act (NSLA). The HHFKA specifies that such nutrition standards apply to all foods sold (a) outside the school meal programs; (b) on the school campus; and (c) at any time during the school day. In addition, the HHFKA requires that such standards be consistent with the most recent Dietary Guidelines for Americans and that the Secretary consider authoritative scientific recommendations for nutrition standards; existing school nutrition standards, including voluntary standards for beverages and snack foods; current State and local standards; the practical application of the nutrition standards; and special exemptions for infrequent school-sponsored fundraisers (other than fundraising through vending machines, school stores, snack bars, a la carte sales and any other exclusions determined by the Secretary). These proposed changes are intended to improve the health and well-being of the Nation's children, increase consumption of healthful foods during the school day and create an environment that reinforces the development of healthy eating habits.

The standards for food and beverages proposed in this rule represent minimum standards that local educational agencies, school food authorities and schools would be required to meet. State agencies and/or local schools would have the discretion to establish their own standards for non-program foods sold to children should they wish to do so, as long as such standards are consistent with the final minimum standards. This rule also proposes to codify a provision of the HHFKA that requires schools participating in the NSLP to make free, potable water available to children in the place lunches are served during meal service.

Summary of Major Provisions

In formulating the proposal, USDA considered the Institute of Medicine's (IOM) 2007 *Nutrition Standards for Foods in Schools: Leading the Way Toward Healthier Youth* report, and reviewed nutrition standards developed by other entities, including existing State and local standards, and voluntary standards developed by organizations such as the Alliance for a Healthier Generation (AHG). Rather than offer a

single approach, the proposal offers alternatives in several areas and requests comment on the relative merits of each of the alternatives. (These are noted below.)

Food Requirements—Under the proposed rule, any food sold in schools must:

(1) Be either a *fruit,* a *vegetable,* a *dairy product,* a *protein food,* a *''whole-grain rich'' grain product* (50% or more whole grains by weight or have whole grains as the first ingredient), or *a combination food* that contains at least ¼ cup of fruit or vegetable; or

(2) Contain 10% of the Daily Value (DV) of a nutrient cited as a public health concern in the 2010 Dietary Guidelines for Americans (DGA) (calcium, potassium, vitamin D, or fiber).

Additionally, foods sold must meet a range of calorie and nutrient requirements:

- Total fat must be ≤35% of calories; *saturated fat* must be <10% of calories; and *trans fat* must be 0g as stated on the label. Exemptions are provided for reduced fat cheese; nuts and nut butters without other ingredients and seafood with no added fat.
- Snack items shall contain ≤200 milligrams of sodium. For entrée items, sodium levels must be ≤480 milligrams per portion, for non-NSLP/SBP entrée items.
- For *total sugar levels* the proposal includes two alternatives: one is ≤35% of calories and the other is ≤35% of weight. Exemptions are provided for fruits and vegetables packed in juice or extra-light syrup and for certain yogurts.
- Snack items have a limit on calories of ≤200 calories per portion. Non-NSLP/SBP entrée items have a calorie limit of ≤350 calories.

The proposal includes two alternatives to exempt one set of foods from the food requirements—NSLP/SBP entrees and side dishes sold a la carte. The first alternative would subject NSLP/SBP menu items only to the fat and sugar standards with no restrictions regarding timeframes for the service of such items sold a la carte. The second alternative would exempt any menu item served as part of the NSLP or SBP, subject to specific timeframe restrictions as outlined in the proposed rule (the day that they are served in a meal or within 4 operating days of service).

Beverage requirements

Under the proposal, all schools may sell plain water, plain low fat milk, plain or flavored fat-free milk and milk alternatives permitted by NSLP/SBP, and 100% fruit/vegetable juice. Portion sizes of milk and juice vary by the age of students. Elementary schools may sell up to 8-ounce portions. Middle schools and high schools may sell up to 12-ounce portions.

Beyond this, the proposal offers additional beverage options in high schools. These include 20 ounce servings or less for calorie-free, flavored and/or unflavored carbonated water and other calorie-free beverages that comply with the Food and Drug Administration (FDA) standard of <5 cals/serving.

Additionally, the proposal would allow *12 ounce* servings of other beverages within a specified calorie limit. The proposal offers two alternatives for this limit. The first is ≤ 40 cals/8 oz serving (or ≤ 60 cals/12 oz serving), and the second is 50 cals/8 oz serving (or 75 cals/12 oz serving). Such beverages shall not be available in the meal service area during the meal service periods.

Accompaniments—The proposal requires accompaniments to be pre-portioned and offered only when food is sold. In addition, accompaniments must ''fit'' within the nutrient profile of the food that they accompany.

Fundraisers—The sale of food items that meet the proposed nutrition requirements at fundraisers would not be limited in any way under the proposed rule. However, the law permits USDA to allow for a limited number of fundraisers to sell food and beverage items that do not meet the proposed nutrition requirements. Because of the wide variety of options available with regard to the frequency of fundraiser exemptions, the proposed rule includes two alternative approaches that provide discretion to State agencies in determining the frequency with which such fundraising activities may take place, and requests other suggestions. The proposed standards would not apply to non-school hours, weekends and off-campus fundraising events.

Costs and Benefits

The principal benefit of the proposed rule is improvement in public health. The primary purpose of the proposed rule is to ensure that competitive foods are consistent with the most recent DGA, effectively holding competitive foods to the same standards as other foods sold at school during the school day. The link between poor diet and health problems (such as childhood obesity) is a matter of particular policy concern because the relevant health problems produce significant social costs; imposing nutrition standards on competitive foods is one way to ensure that children are provided with healthy food options throughout the school day.

We anticipate the proposed rule will result in significant changes to the nutritional quality of competitive foods available in schools, although it is not possible to quantify those benefits on overall diets or student health. Excess body weight has long been demonstrated to have adverse health, social, psychological, and economic consequences for affected adults, and recent research has also demonstrated that excess body weight has negative impacts for obese and overweight children. Ancillary benefits, which are also not quantifiable at the present time, may also be realized by the nutrition standards in the proposed rule, e.g., improving the nutritional value of competitive foods will support the efforts of parents to promote healthy choices at home and at school, reinforce school-based nutrition education and promotion efforts, and contribute significantly to the overall effectiveness of the school nutrition environment in promoting healthful food and physical activity choices.

The proposed rule requires schools to improve the nutritional quality of foods offered for sale to students outside of the Federal school lunch and school breakfast programs. The new standards apply to foods sold à la carte, in school stores, snack bars, or vending machines. Upon implementation of the rule, students will face new food choices from these sources. The new choices will meet standards for calories, fat, saturated fat, sugar, and sodium, and have whole grains, low fat dairy, fruits, vegetables, or protein foods as their main ingredients. Our analysis examines a range of possible behavioral responses of students and schools to these changes. To estimate the effects on school revenue, we look to the experience of school districts that have adopted or piloted competitive food reforms in recent years. While no State standard aligns to all of the provisions of the proposed rule, these State programs offer the closest ''real-world'' analogue to the proposal.

The available information indicates that many schools have successfully introduced competitive food reforms with little or no loss of revenue. In some of those schools, losses from reduced sales of competitive foods were fully offset by increases in reimbursable meal revenue. In other schools, students responded favorably to the healthier options, and competitive food revenue increased or remained at previous levels.

But not all schools that adopted or piloted competitive food standards fared as well. Some of the same studies and reports that highlight school success

stories note that other schools sustained losses after implementing similar standards. The competitive food revenue lost by those schools was not offset (at least not fully) by revenue gains from the reimbursable meal programs.

We present a series of possible school revenue effects in this analysis that reflect the variation in outcomes across these case studies, differences in the adopted nutrition standards and implementation strategies, and differences in the schools' economic circumstances. This discussion illustrates a range of potential outcomes; the limited nature of available data and the substantial variation in school experiences to date prevent any assessment of the most likely outcome.

The analysis included in the proposed rule examines the possible effects of the proposed rule on school revenues from competitive foods, the administrative costs of complying with the rule and the benefits to school children.[1] The magnitude of these effects is subject to considerable uncertainty; the ultimate impact of the rule will be determined by the manner in which schools implement the new standards and how students respond.

Background

This rule sets forth proposed provisions to implement sections 203 and 208 of Public Law 111–296, the Healthy, Hunger-Free Kids Act of 2010 (HHFKA), which set conditions on schools that participate in programs authorized under NSLA and the CNA. The largest of these programs are the National School Lunch Program (NSLP) and the School Breakfast Program (SBP). NSLP is available to over 50 million children each school day; an average of 31.8 million children per day received a reimbursable lunch in Fiscal Year (FY) 2011. In that same FY, SBP served an average of 12.1 million children daily. Schools that participate in the NSLP and SBP receive Federal reimbursement and USDA Foods (donated commodities) for lunches that meet program requirements. The level of Federal support provided varies by the household income of the participating child, with the highest reimbursements to schools for meals provided free to the children eligible for such meals.

Availability of Water During the Meal Service

Section 203 of the HHFKA amends section 9(a) of the NSLA (42 U.S.C. (1758(a)) by requiring that schools participating in the NSLP make potable water available to children at no charge in the place where lunches are served during the meal service. This is a nondiscretionary requirement of the HHFKA that became effective October 1, 2010.

There are a variety of ways that schools can choose to implement this requirement. For example, schools can offer water pitchers and cups on lunch tables, a water fountain, or a faucet that allows students to fill their own bottles or cups with drinking water. Whatever method is chosen, the water must be available without restriction in the location where meals are served.

While potable water is required to be made available to students, it is not considered part of the reimbursable meal, and students are not required to take water. There is no separate funding available for this provision and reimbursement may not be claimed. However, reasonable costs associated with providing potable water would be an allowable cost to the non-profit school food service account. Please note that this proposed rule would also apply to afterschool snack service claimed through the NSLP. In addition, while the statute does not specifically require that potable water be served in the School Breakfast Program, the availability of water during all meal services is encouraged.

The Department recognizes that some food service areas and/or procedures may require significant changes to properly implement this provision, and guidance has been provided to State agencies to use with schools. The Department issued an implementation memorandum entitled ''Child Nutrition Reauthorization 2010: Water Availability During National School Lunch Program Meal Service,'' SP 28–2011, on April 14, 2011, and participated in the Food Research and Action Center's webinar, ''Strategies for Success: Making the Most of the New School Water and Milk Requirements,'' on May 24, 2011. On July 12, 2011, SP 28–2011 was revised to provide more detailed guidance in the form of a series of questions and answers regarding the implementation of the water requirement. This memorandum is available on the FNS Web site at *http://www.fns.usda.gov/cnd/governance/policy.htm.*

State agencies and local school food authorities are reminded that schools were required to comply with this provision not later than the beginning of School Year 2011–12. This nondiscretionary requirement is included in this proposed rule as an amendment to § 210.10(a)(1).

Nutrition Standards for Food Sold in Schools in Competition With School Meals

Federal child nutrition programs play a critical role in providing nutritious, balanced meals to children and promoting healthy lifestyles. Major strides have been made in recent years to improve the quality of meals served to children through Federal child nutrition programs. Despite this significant progress, however, considerable work remains to be done to improve children's diets. Available research has consistently shown that the diets of children in the U.S. do not meet current national dietary recommendations for nutrition and health. Overall, children today have diets that are low in fruits, vegetables, whole grains, and dairy foods and high in sodium, fat and added sugars. The 2010 DGA recommend that Americans increase their consumption of whole grains, but according to the U.S. Department of Health and Human Services (DHHS) report, *Healthy People 2010,* only 7 percent of children ages 2 to 19 years currently meet this recommendation.

The link between poor diets and health problems such as childhood obesity are a matter of particular policy concern given their significant social and economic costs. Obesity, in addition to nutrition and physical activity, has become a major public health concern in the U.S.[2] According to data from the National Health and Nutrition Examination Survey 2007–2008, 34 percent of the U.S. adult population is obese and an additional 34 percent are overweight (Ogden and Carroll, 2010). The trend towards obesity is also evident among children; 33 percent of U.S. children and adolescents are now considered overweight or obese (Beydoun and Wang, 2011), with current childhood obesity rates four times higher in children ages 6 to 11 than they were in the early 1960s (19 vs. 4 percent), and three times higher (17 vs. 5 percent) for adolescents ages 12 to 19 (IOM, 2007b, p. 24). These increases are shared across

[1] For simplicity and because the consumption of competitive foods at breakfast is relatively low compared to the consumption of competitive foods at lunch, we model the shift from competitive foods to program meals as one that takes place at lunchtime only. SNDA–III found that competitive foods were consumed by 29 percent of NSLP non-participants during the lunch period in SY 2004–2005 (Gordon, et al., 2007, vol. 2, table VI.9, p. 196), but that competitive foods were consumed by just 5 percent of SBP non-participants during the breakfast period (vol. 2, table VII.9, p. 264).

[2] HealthyPeople.gov. ''Nutrition, Physical Activity, and Obesity. Available at *http://healthypeople.gov/2020/LHI/nutrition.aspx?tab=data.*

all socio-economic classes, regions of the country, and have affected all major racial and ethnic groups (Olshansky, et al., 2005).

Available health research [3] shows a strong association between obesity and other chronic diseases, including cardiovascular disease, hypertension, and diabetes. Cardiovascular disease is the leading cause of death in America, resulting in 500,000 annual deaths. Risk factors for cardiovascular disease occur with much greater frequency among obese children than they do among normal weight children. One quarter of children ages 5 to 10 show early warning signs for heart disease, such as elevated blood pressure or high cholesterol.

This and other evidence indicates a need to improve the diets of children. Since a significant portion of calories consumed by children takes place at school, improving the nutritional profile of all foods sold in school beyond Federally-reimbursable meals is critical to improve the diets and overall health of American children more generally, and to ensure that more children from all income levels adopt the kind of healthful eating habits and lifestyles that will enable them to live healthier, more productive lives.

Section 208 of the HHFKA amended Section 10 of the CNA providing the Secretary new authority to establish nutrition standards for all foods and beverages sold outside of the Federal child nutrition programs in schools. Specifically, the HHFKA amended the CNA to require that the Secretary promulgate proposed regulations to establish nutrition standards for foods sold in schools other than those foods provided under the CNA and the NSLA. The provisions specify that the nutrition standards shall apply to all foods sold (a) outside the school meal programs; (b) on the school campus; and (c) at any time during the school day.

The provisions further stipulate that such standards be consistent with the most recent DGA and that the Secretary consider authoritative scientific recommendations for nutrition standards; existing school nutrition standards, including voluntary standards for beverages and snack foods and current State and local standards; the practical application of the nutrition standards; and special exemptions for infrequent school-sponsored fundraisers (other than fundraising through vending machines, school stores, snack bars, a la carte sales and any other exclusions determined by the Secretary).

Prior to enactment of the HHFKA, the Secretary's authority to regulate the types of foods sold in schools was limited to meal pattern requirements for meals served under NSLP and SBP and other foods sold in the food service areas during meal periods. Restrictions on the sale of foods of minimal nutritional value (FMNV) in food service areas during meal periods are found at 7 CFR 210.11 and 220.12 and Appendix B to parts 210 and 220. The term ''food service areas'' means any place where school meals are being served or consumed, including classrooms and multipurpose rooms that double as cafeterias during meal periods. The Secretary did not have authority to establish regulatory requirements for foods sold in other areas of the school campus or at other times during the school day.

While meals provided through the Federal school meal programs must meet certain nutritional requirements, schools may also provide foods and beverages outside of these programs, such as a la carte items in the school cafeteria as well as those sold through vending machines, school stores, school fundraisers, and snack bars. These foods are commonly referred to as ''competitive foods'' because they are sold in competition with foods offered in school meal programs. The requirement that local educational agencies have local school wellness policies, pursuant to Section 9A of the NSLA, 42 USC 1786b, was initially established in the Child Nutrition and WIC Reauthorization of 2004, P.L. 108–265, and further strengthened by section 204 of the HHFKA. As part of local wellness policies, schools are encouraged to establish their own standards for competitive foods. In many cases, school food authorities have been very successful in increasing the number of healthy offerings in the area of competitive food sales and developing standards for the sale of such foods and beverages in schools; however, implementation of such policies has been varied. Likewise, voluntary certification initiatives, such as USDA's HealthierUS School Challenge (HUSSC) and the Healthy Schools program of the Alliance for a Healthier Generation, set criteria for competitive foods and beverages when schools offer them, but not all schools participate.

The goal of both the changes to the nutrition requirements for NSLP and SBP meals required by the HHFKA and contained in the final rule, *Nutrition Standards in the National School Lunch and School Breakfast Programs,* (77 FR 4088, *January* 26, 2012), and the standards for competitive foods outlined in this proposed rule is to improve the health and well being of the Nation's children, increase consumption of healthful foods during the school day and to create an environment that reinforces the development of healthy eating habits.

This proposed rule includes standards for both foods and beverages sold in schools outside of the Federal child nutrition programs, in accordance with the intent of the HHFKA. Specifically, the HHFKA clearly directs the Secretary to consider authoritative scientific recommendations (which include those for both food and beverages) as well as existing State, local and other voluntary standards for beverages and snack foods. All such standards include beverage standards. In addition, the Secretary's authority to set standards with regard to reimbursable meals has historically included beverages, so it is reasonable to believe that in extending this authority to other foods sold in schools, Congress intended to include beverage standards.

Alternative approaches to several of the proposed provisions are described in the preamble of this rulemaking and presented in the proposed regulatory language, in order to solicit public comment on their merits. Please note that the order in which these alternatives are presented is not intended to indicate a preferred approach.

Considerations

As previously indicated, the nutrition standards established by the Secretary must be consistent with the most recent DGA, which, for the purposes of developing this proposed rule, are the 2010 Dietary Guidelines for Americans released on January 31, 2011. The guidelines are available at *http://www.cnpp.usda.gov/DietaryGuidelines.htm*. In developing the competitive food standards, the Secretary is also directed by the HHFKA to consider authoritative scientific recommendations for nutrition standards; existing school nutrition standards, including voluntary standards for beverages and snack foods and State and local standards; and the practical application of the nutrition standards. As part of USDA's review of authoritative scientific recommendations for nutrition standards, the Agency gave consideration to the National Academies' Institute of Medicine's (IOM) 2007 report entitled *Nutrition*

[3] See, for example, *Preventing Childhood Obesity: Health in the Balance* by Jeffrey P. Koplan, Catharyn T. Liverman, and Vivica A. Kraak (Editors), Committee on Prevention of Obesity in Children and Youth, Washington, DC: The National Academies Press, 2005.

Standards for Foods in Schools: Leading the Way Toward Healthier Youth (available at: *http://www.cdc.gov/HealthyYouth/nutrition/standards.htm*).

In addition, the Department conducted a broad review of nutrition standards developed by other entities. These included USDA's HUSSC standards, existing State and local school nutrition standards for foods and beverages sold in competition with school meals, and existing voluntary standards and recommendations that have been developed by various organizations such as the National Alliance for Nutrition and Activity and the Alliance for a Healthier Generation.

The Department also solicited input from Federal child nutrition program stakeholders, including nutrition and health professionals, academia, industry, interest groups and the public through a variety of channels. Input gathered from these various sources has served to assist the Department in formulating the standards and options proposed in this rule. The practical application of the competitive food nutrition standards in school settings was a key consideration for all of the proposed standards. Additionally, over 4,400 schools to date have been recognized through the HUSSC initiative and have adopted strong competitive foods policies as part of their application for recognition. The HUSSC criteria for competitive food policies is based on IOM recommendations that promote offering competitive food items that are limited in calories and low in total fat, trans fat, saturated fat, sugar, sodium, and that also limit the types and portion sizes of beverages that can be sold in competition with the reimbursable meal.

This proposed rule is predicated on the principle that the present and future health and well-being of school-age children is profoundly affected by dietary intake and the maintenance of a healthy weight. Schools contribute to current and lifelong health and dietary patterns and are uniquely positioned to model and reinforce healthful eating behaviors in partnership with parents, teachers, and the broader community. The practice of food sales in competition with federally-reimbursable program meals and snacks is widespread. In school year (SY) 2004–2005, 82 percent of all schools—and 92 percent of middle and high schools—offered a la carte foods at lunch. Vending machines were available in 52 percent of all schools and 26 percent of elementary schools, 87 percent of middle schools and 98 percent of high schools (Gordon, et al., 2007; SNDA–III, Volume 1, pp 102–114). Because all foods and beverages available on the school campus represent significant opportunity for the intake of calories and foods and nutrients encouraged by the DGA, competitive food standards should be designed to meet such nutrition recommendations.

Nutrition standards for all foods and beverages sold in schools should be considered in the context of new meal patterns for the Federal school meal programs and the goals of improving the nutrition environment of our Nation's schools. The intent of this proposal is to support the federally-reimbursed school nutrition programs as the major source of foods and beverages offered at school and to ensure that all foods and beverages sold on the school campus during the school day will contribute to an overall healthful eating environment. These proposed standards do not exclude any of the USDA NSLP/SBP Meal Pattern food components or the DGA subgroups as long as the product meets the general standards proposed for allowable competitive foods. It is intended that these standards for competitive foods be simple in order to encourage the inclusion of the ''Foods and Nutrients to Increase'' identified in the 2010 DGA, and that the standards be practical for application at the school or district level.

The proposed standards and the proposed exceptions to the standards include numerous areas of consensus and/or consistency among the various source recommendations that were reviewed. In addition, there are a number of areas where existing recommendations and/or voluntary or State/local standards vary considerably in their specific approach to issues. We carefully considered each of these. As a result, where appropriate in these areas, the Department has proposed two or more options for implementing standards and is interested in receiving comments on which of these options best achieves the objectives of the DGA while considering the practical application of standards in a school setting.

Definitions

The HHFKA stipulates that the nutrition standards for competitive food shall apply to all foods and beverages sold: (a) Outside the school meals programs; (b) on the school campus; and (c) at any time during the school day. Therefore, for the purpose of implementing section 208 of the HHFKA, this rule includes proposed definitions for ''competitive food'', ''school campus'' and ''school day''.

There are many definitions of ''school day'' currently utilized by schools across the country. In almost every instance, such definitions apply to the instructional day, rather than to the availability of food or meal services in schools during the school day. The definitions proposed in this rule deal exclusively with the application of the proposed competitive food standards and are intended to have no impact whatsoever on any definition of instructional day or school campus that is established by a State or a local educational agency or school for other purposes. *Competitive food* is proposed to be defined as all food and beverages sold to students on the *School campus* during the *School day,* other than those meals reimbursable under programs authorized by the NSLA and the CNA. *School day* is proposed to be defined, for the purpose of competitive food standards implementation, as the period from the midnight before, to 30 minutes after the end of the official school day. Finally, *School campus* is proposed to be defined, for the purpose of competitive food standards implementation, as all areas of the property under the jurisdiction of the school that are accessible to students during the school day.

The intent of the proposed definitions of school day and school campus is to provide simple and straightforward criteria to ensure that food that does not meet the standards outlined in this proposed rule is not sold to students on the school campus during the school day. Given the many activities, programs and schedules established by schools, it is not possible to specify in regulations a precise time for the start of the school day; therefore, this rule proposes that the sale of competitive food to students be prohibited from the midnight before, to 30 minutes after the end of the official school day (i.e., instructional day). Competitive food, school day, and school campus are defined in § 210.11(a).

In addition, § 210.11(b)(4) of this rule proposes that these nutrition standards for competitive foods apply to any program operating in the school on the school campus during the school day that is serving meals reimbursed under any program authorized under the NSLA or the CNA. Foods that do not meet the nutrition standards outlined in this proposal should not be available for sale to students on the school campus during the school day.

Nutrition Standards for Foods and Beverages

The standards proposed in this rule represent minimum standards that local

educational agencies, school food authorities and schools must meet. State agencies and/or local schools have the discretion to establish their own competitive food standards should they wish to do so, as long as such standards are consistent with the final minimum standards. This option is included in § 210.11(b)(1) of the proposed rule. Competitive food standards apply to all age groups of students. Additionally, the proposed rule includes separate standards for foods and beverages.

General Nutrition Standards for Competitive Foods

The IOM in their report entitled *Nutrition Standards for Foods in Schools: Leading the Way Toward Healthier Youth* categorized food and beverages into two tiers, based on the extent of their consistency with the DGA. Tier 2 foods are not relevant to this proposal since such foods are those recommended to only be served to high school students after the school day. Tier 1 foods and beverages are consistent with ''foods to be encouraged'' as defined in the DGA and are the basis for many of the provisions of this proposed rule. IOM Tier 1 foods are defined as fruit, 100% fruit and vegetable juices, vegetables, whole grains and related combination products, and nonfat and low-fat dairy products *and* NSLP food items that are part of the reimbursable meal that are also sold a la carte that meet fat and sugar limits outlined in the IOM report. This proposed rule is generally consistent with the IOM standards and the DGA in that it permits the sale of Tier 1 foods as well as additional foods containing a significant amount of one of the four nutrients of public health concern, and/or fruits/vegetables.

To be an allowable competitive food in schools, an item shall:

(1) Meet all of the proposed competitive food nutrient standards; and

(2) Be a grain product that contains 50 percent or more whole grains by weight or have whole grains as the first ingredient *or* be one of the non-grain main food groups as defined by the 2010 DGA: a fruit, vegetable, dairy product, protein food (meat, beans, poultry, seafood, eggs, nuts, seeds, etc.); or

(3) Contain 10 percent of the Daily Value (DV) of a naturally occurring nutrient of public health concern from the DGA (e.g., calcium, potassium, vitamin D or dietary fiber); or

(4) Be a combination food that contains at least ¼ cup of fruit or vegetable.

This proposal stipulates that, in cases in which water is the first ingredient listed for a food item, the second ingredient must be one of the above. Below is a brief summary chart depicting the proposed standards contained in this rule. A thorough discussion of each standard follows.

PROPOSED COMPETITIVE FOODS STANDARDS

Food/nutrient	Standard	Exemptions to the standard
General Standard for Competitive Food.	To be allowable, a competitive FOOD item must: (1) meet all of the proposed competitive food nutrient standards; and (2) be a grain product that contains 50% or more whole grains by weight or have whole grains as the first ingredient *or* be one of the non-grain main food groups: a fruit, vegetable, dairy product, protein food (meat, beans, poultry, seafood, eggs, nuts, seeds, etc.), or (3) contain 10% of the Daily Value (DV) of a naturally occurring nutrient of public health concern (i.e., calcium, potassium, vitamin D or dietary fiber) or; (4) be a combination food that contains at least ¼ cup of fruit or vegetable. If water is the first ingredient, the second ingredient must be one of the above.	• Fresh, frozen and canned fruits and vegetables with no added ingredients except water or, in the case of fruit, packed in 100% juice or extra light syrup, exempt from all proposed nutrient standards.
NSLP/SBP Entrees and Side Dishes Sold A la Carte.	Alternative A1: NSLP/SBP entrees and side dishes sold a la carte exempt from all standards except the fat and sugar standards (≤35% of total calories from fat or ≤35% of calories or weight from total sugar (See Alternative C1 and C2)) ; or Alternative A2: NSLP/SBP entrees and side dishes (except grain based dessert products) sold a la carte exempt from all standards. *Alternatives B1 and B2 describe two approaches to the timing of service associated with this exemption.*	
Grain Items	Acceptable grain products must include 50% or more whole grains by weight or have whole grains as the first ingredient.	
Total Fats	Dietary fat per portion as packaged: ≤35% of total calories from fat per portion as packaged.	• Reduced fat cheese; • Nuts and seeds and nut/seed butters. Exemption does *not* extend to combination products that contain nuts, nut butters or seeds or seed butters with other ingredients such as peanut butter and crackers, trail mix, chocolate covered peanuts, etc.; • Products consisting of only dried fruit with nuts and/or seeds with no added nutritive sweeteners or fat; • Seafood *with no added fat.*
Saturated Fats	• <10% of total calories per portion as packaged	• Reduced fat cheese
Trans Fats	• Zero grams of trans fat per portion as packaged (≤0.5 g per portion).	

PROPOSED COMPETITIVE FOODS STANDARDS—Continued

Food/nutrient	Standard	Exemptions to the standard
Sodium	• Snack and side items: ≤ *200 mg* sodium per portion as packaged for non NSLP/SBP snack items; • Entrée items: ≤480 mg sodium per portion for non-NSLP/SBP entrée items.	
Total Sugars	• Alternative C1: ≤35% of calories from total sugars in foods; or • Alternative C2: ≤35% of weight from total sugars in foods.	• Fresh, frozen and canned fruits/vegetables with no added sweeteners except for fruits packed in 100% juice or extra light syrup; • Dried whole fruits/vegetables, dried whole fruit/vegetable pieces; and dried dehydrated fruits/vegetables with no added nutritive sweeteners. • Lowfat/nonfat yogurt with less than 30 grams of sugar per 8 ounces.
Calories	• ≤200 calories per portion as packaged including any added accompaniments such as butter, cream cheese, salad dressing etc. for non NSLP/SBP snack items and side dishes sold a la carte;. • ≤350 calories for non NSLP/SBP entrée items sold a la carte.	
Accompaniments	• Use of accompaniments should be limited when food is sold to students in school. All accompaniments shall be pre-portioned and must be included in the nutrient profile as a part of the item served and meet all proposed standards;	
Caffeine	Elementary and Middle School Foods and beverages must be caffeine-free, with the exception of trace amounts of naturally-occurring caffeine substances. No caffeine restriction for high school students.	
Beverages	Elementary School. • No caffeinated beverages; • Plain water (no size limit); • Low fat milk, plain (≤8 oz); • Non fat milk, plain or flavored (≤8 oz), including nutritionally equivalent milk alternatives as permitted by the school meal requirements; and • 100% fruit/vegetable juice (≤8 oz). Middle School. • No caffeinated beverages; • Plain water (no size limit); • Low fat milk, plain (≤12 oz); • Non fat milk, plain or flavored (≤12 oz) including nutritionally equivalent milk alternatives as permitted by the school meal requirements; and • 100% fruit/vegetable juice (≤12 oz). High School. • Plain water (no size limit); • Low fat milk/plain (≤12 fl. oz.); • Non fat milk, plain or flavored (≤12 fl. oz.), including nutritionally equivalent milk alternatives as permitted by the school meal requirements; • 100% fruit/vegetable juice (≤12 fl. oz.); • Calorie-free, flavored and/or unflavored, caffeinated or non-caffeinated carbonated water allowed (≤20fl. oz), but *not* during the meal service periods; • Other calorie free caffeinated or non-caffeinated beverages that comply with the FDA standard of less than 5 kcals/serving. (≤20 fl. oz.), allowed, but *not* during the meal service periods; and • Alternative D1: Other caffeinated or non-caffeinated beverages (≤40 calories/8 oz serving or ≤60 calories/12 oz serving) in ≤12 oz servings allowed, but not during the meal service periods; or. • Alternative D2: Other caffeinated or non-caffeinated beverages (≤50 calories/8 oz or ≤75 calories/12 oz serving) in ≤12 oz servings, but not during the meal service periods.	

The following discussion outlines the nutrition standards for allowable competitive foods as proposed in this rule at § 210.11.

General Exemption of NSLP and SBP Entrees and Side Dishes

This rule proposes two alternatives by which any menu item (both entrees and side dishes) provided as part of the NSLP and/or SBP school meal would be exempt from all or some of the proposed competitive food nutrition standards, with the exception of grain based dessert products which must meet all standards in order to be served.

The first alternative (A1) would align such an exemption with the IOM recommendations related to NSLP and SBP menu items. If items are served in the reimbursable meal, they would be exempt from all of the proposed nutrition standards except they would still have to meet the limits on fat and sugar. As discussed later in this preamble, the proposed limit for fat is ≤35% of total calories from fat per portion as packaged. For sugar, two alternatives are proposed: Alternative C1: ≤35% of calories from total sugars in foods; or Alternative C2: ≤ 35% of weight from total sugars in foods. The purpose of including this alternative for meals is to ensure that the improvements that will result from the updated nutrition standards would not be undermined.

The second alternative (A2) would exempt all menu items provided as part of the NSLP or SBP reimbursable meal from the proposed competitive food standards, with the exception of grain based dessert products which must meet all standards in order to be served. For this alternative, the rule also proposes two alternatives for comment with regard to the frequency of allowable sale of the NSLP/SBP menu items as competitive foods which are described as Alternatives (B1) and (B2) below. These NSLP/SBP menu items would have to be served in the same or smaller portion sizes as in the NSLP or SBP to be allowable. In general, the proposed exemption for NSLP/SBP menu items supports the new school meal patterns and the concept of school meals as being healthful.

The first alternative proposed regarding the frequency of allowable service of the exempted NSLP/SBP menu items (B1) would allow an exemption to the proposed nutrient standards for competitive foods for NSLP and SBP menu items *on the same day* that the items were served in the school meals program. While this may limit flexibility for the school food service and prevent the service of some leftover entrees and/or side dishes during the menu cycle, this option would alleviate concerns regarding the frequency with which particular food items are available.

The second alternative (B2) would allow an exemption to the proposed nutrient standards for competitive foods for NSLP and SBP menu items served within four operating days of service in the programs. This option provides an increase in flexibility for the school food service.

The Department seeks comments on these alternatives, identified at Alternatives B1and B2 in § 210.11(c)(3) of the proposed rule.

Naturally Occurring Nutrients

One of the general standards proposed in this rule is that, in order to be allowable, food items must contain 10% of the Daily Value (DV) of a naturally occurring nutrient of public health concern: calcium, potassium, vitamin D, and dietary fiber. Including the 10% DV as a method to determine the foods that may be sold in schools encourages consumption of these nutrients.

The Department is interested in receiving comments from the public as to whether or not food items that contain only naturally occurring nutrients should be allowed in this rule, or whether food items to which specific nutrients of concern have been added should also be allowable.

For example, if only naturally occurring nutrients were specified, a product may be formulated to have 10% calcium by including ingredient(s) in the product formulation that are naturally high in calcium such as non-fat dry milk solids, or cheese. Obviously, the ingredient(s) used and the amount needed would vary depending on the product and may not be feasible for some products, but the nutrients from these ingredients would be included in meeting the 10% DV level. Using this method would not allow the addition of the discrete nutrient (many forms exist for the addition of calcium to food, such as tricalcium phosphate, calcium citrate malate, calcium lactate, etc.) to count toward meeting the 10% DV requirement. The rationale to limit the products to the naturally occurring nutrients is to limit the consumption of products to which specific nutrients of concern have been added and encourage consumption of whole foods or foods closer to their whole state as encouraged by the DGA. One concern with this approach is that schools may not be able to recognize when a specific nutrient of concern has been added to a product or when the nutrient is naturally occurring. Fortifications are often not highlighted on the label and the nutrient facts panel does not currently make any distinction between naturally occurring nutrients and those nutrients available in a food through fortification. This requirement may be found in § 210.11(c)(2)(iv) of the proposal.

Combination Foods

Since many of the foods available to students contain a combination of ingredients, for the purposes of this proposal, combination foods are defined as products that contain two or more components that represent two or more of the recommended food groups as specified in the DGA (fruit, vegetable, dairy, protein or grains). This proposed definition may be found at § 210.11(a)(4).

Fruits and Vegetables

To be consistent with both the DGA and the IOM recommendations, this rule proposes that fresh, frozen and canned fruits and vegetables *with no added ingredients except water or, in the case of fruit, packed in 100 percent juice or extra light syrup,* be exempt from all the nutrient standards included in this rule. According to the DGA, fruits and vegetables are nutrient dense; greater consumption of such foods in the diet is encouraged. This provision is included at § 210.11(d) of this proposed rule.

Grain Items

This rule proposes that acceptable grain products must include whole grains. To qualify as an allowable competitive food, grain products shall meet at least one the following criteria as well as meet all of the proposed nutrient standards:

(1) Contain 50% or more whole grains by weight; or

(2) Have whole grains as the first ingredient.

This standard is consistent with the DGA recommendations, the NSLP meal pattern standards and the HUSSC whole grain requirement. It is also practical because it can be easily identified by reading a product label. This provision is included at § 210.11(e).

Total Fats

To qualify as an allowable competitive food, this proposal specifies that not more than 35 percent of the total calories per portion as packaged shall be derived from fat. Nuts and seeds, peanut and other nut butters, seafood, and reduced fat cheese would be exempt from this standard. This standard is identical to the IOM recommendation for total fats. However,

the Department is proposing to allow the following exemptions to the total fat limitation. Please note that requirements and exemptions other than total fat mentioned below are discussed later in this preamble under the applicable section.

(1) Reduced fat cheese is exempt from the total fat and saturated fat standard, but subject to the trans fat, calorie, sugar and sodium standards. The exemption for reduced fat cheese is based primarily on the availability of lower fat cheeses that children find palatable and the recognition that reduced fat cheese is a source of calcium, a nutrient of concern, and contributes to overall bone health. In addition, this exemption is consistent with voluntary standards that have been reviewed during the course of developing this proposal.

(2) Nuts and seeds and nut/seed butters are exempt from the total fat standard, but subject to the saturated fat, trans fat, calorie, sugar, and sodium standards. This exemption does *not* extend to combination products that contain nuts, nut butters or seeds or seed butters with other ingredients such as peanut butter and crackers, trail mix, chocolate covered peanuts, etc. This exemption from the total fat standard allows the inclusion of nuts and seeds within reasonable calorie amounts. Without such an exemption, nuts and seeds could not be sold alone without being combined with some other product like added sugars or refined grain, which is not the intent of these competitive food nutrition standards. Nuts, seeds and nut/seed butters are nutrient-dense, good sources of monounsaturated and polyunsaturated fatty acids, some of which are essential, and are sources of many vitamins and minerals, as well as dietary fiber. In addition, ensuring the allowance of nuts and seeds provides a shelf stable, vegetarian-friendly protein source.

(3) Products that consist of only dried fruit with nuts and/or seeds with no added nutritive sweeteners or fat are exempt from the total fat and sugar standard; but are subject to the saturated fat, trans fat, calorie and sodium standards, for reasons similar to those cited above. In addition, dried fruit has the same nutritional benefits of fruits and will assist in helping children meet their daily fruit requirements.

(4) Seafood *with no added fat* is exempt from the total fat requirement in order to increase omega-3 fatty acids; but still subject to the proposed sugar, saturated fat, trans fat, calorie and sodium standards.

In summary, reduced fat cheese, nuts, seeds and nut/seed butters and dried fruit are popular food items among school-aged children and can make a positive contribution to overall health, especially since these food items must meet the other nutrient standards proposed. These provisions may be found at § 210.11(f).

Saturated Fats

To qualify as an allowable competitive food, it is proposed that less than 10% of the total calories per portion of a food be derived from saturated fats. Cheese is exempt from the total fat and saturated fat standard if it is reduced fat cheese, as discussed above. However, such reduced fat cheese products remain subject to the proposed calorie, trans fat, sugar and sodium standards outlined in this rulemaking. This standard is also consistent with the DGA and may be found in § 210.11(g) of this proposed rule.

Trans Fats

It is proposed that allowable competitive foods contain zero grams trans fat per portion as packaged (not more than 0.5 g per portion). This standard is identical to the IOM and DGA recommendations and may be found in § 210.11(h) of this proposed rule.

Total Sugars

This proposed rule provides two alternatives for comment regarding total sugars in foods. Alternative C1 requires that in order to be considered an allowable competitive food item, no more than 35% of *calories* shall be derived from total sugars in foods. This is identical to the recommendation made by the IOM. Alternative C2 requires that allowable competitive food items shall not contain more than 35% of their *weight* from total sugars in foods. This standard was included in a number of voluntary standards that were reviewed during the development of this proposed rule. The calculations associated with these two alternatives differ. Generally, when sugar by weight is utilized, foods with a higher percentage of calories from total sugar would be allowable as competitive foods in schools. This may also result in an increase in the number/types of foods which may be sold in schools, particularly with regard to dairy products such as ice cream. The Department requests comment on these alternatives.

In addition, ideally, the sugar standard would apply to the added sugars in foods, since added sugars are identified in the 2010 DGA as a food component to reduce. However, because the Nutrition Facts label does not differentiate between added and naturally occurring sugars in foods and beverages, a standard limiting total sugars is the most reasonable standard. Regardless of which measure (total sugars by weight or calories) is utilized, this proposed rule includes the following exemptions to this requirement:

(1) Dried whole fruits or vegetables; dried whole fruit or vegetable pieces; and dried dehydrated fruits or vegetables with no added nutritive sweeteners are exempt from the sugar standard, but are subject to the calorie, total fat, saturated fat, trans fat and sodium standards;

(2) Products that consist of only dried fruit with nuts and/or seeds with no added nutritive sweeteners or fat are exempt from the total fat and sugar standard, but are subject to the calorie, trans fat, saturated fat and sodium standards; and

(3) Flavored and unflavored nonfat and low-fat yogurt with no more than 30 grams of total sugars per 8 ounce serving are exempt from the sugar standard, but are subject to the calorie, total fat, saturated fat, trans fat and sodium standards.

The exemption from the total sugar standard proposed in items (1) and (2) above has been made since those food items are nutrient dense and contribute to total intake of fruit and vegetables, which has been identified in the 2010 DGA as a food group targeted for increased consumption. Since the water has been removed from dried products during processing, it is more calorically dense than fresh fruits and vegetables. For this reason, the calorie standards are proposed to apply to dried fruits and dried vegetables as well as dried fruits mixed with nuts and/or seeds. We acknowledge that for certain dried fruit products, the addition of nutritive sweeteners may be necessary for processing and palatability (i.e. cranberries). Therefore we are requesting feedback from commenters on whether the standard should include specific dried fruit products that require nutritive sweeteners in the total sugars exemption.

The proposed sugar standards are found in § 210.11(i).

Sodium

This rule proposes that allowable entrée items contain no more than 480 mg sodium per portion as served. This standard is identical to the IOM recommendation for entrees.

For purposes of this proposed rule, an entrée item is proposed to be defined in § 210.11(k) as an item that includes only

the following three categories of main dish food items:

(1) A combination food of meat or meat alternate and whole grain-rich bread (for example, turkey sandwich, peanut butter on grain-rich bread, pizza with whole grain-rich crust, hot dog or hamburger on a grain-rich bun, a bean and cheese burrito, nachos with chili and cheese);

(2) A combination food of vegetable or fruit and meat or meat alternate (for example, chef's salad, fruit and cheese platter, chicken vegetable stir-fry); or

(3) A meat or meat alternate alone (e.g., fish filet, Salisbury steak, seafood, egg or chicken) with the exception of yogurt, low-fat or reduced fat cheese, nuts, seeds and nut or seed butters. This exception is being proposed since yogurt, cheese, nuts, seeds and nut or seed butters alone are generally considered to be snack or dessert items, not entrée items.

The Department is proposing that allowable snack items contain no more than 200 mg of sodium per portion as packaged. This standard reflects the IOM recommendation with regard to snack items.

In addition, as previously discussed, this rule proposes to exempt any items sold as part of the school meal during specified periods from all or most (except total fat and sugar) competitive food standards (§ 210.11(c)(3)). The proposed sodium standards are found in § 210.11(j) and (k).

Calories

This rule proposes that, to be considered allowable, snack items shall contain no more than 200 calories per portion as packaged including any added accompaniments such as butter, cream cheese, salad dressing etc. A la carte snack items/side dishes served in the same or smaller portion size as served in the NSLP or the SBP during specific periods would be exempt from this calorie restriction.

This proposed rule stipulates that entrée items sold a la carte shall contain no more than 350 calories per portion as served and meet all of the other nutrition standards specified.

However, consistent with the sodium standard exemption, this rule proposes to exempt entrée items from this calorie requirement if the entrée items sold a la carte are NSLP or SBP entrees that are to be offered during specific periods as part of the reimbursable school meal and are served in the same or smaller portion size as offered in the NSLP or SBP (§ 210.11(c)(3)). The proposed calorie standards are found in § 210.11(j) and (k).

Caffeine

This rule proposes that competitive foods and beverages served to elementary and middle school-aged children must be caffeine-free, with the exception of trace amounts of naturally occurring caffeine substances. This standard is consistent with the IOM recommendation. In the IOM report, it was concluded that although there may be some benefits associated with caffeine consumption among adults, offering foods and beverages containing significant amounts of caffeine to school aged children was not appropriate due to the potential for adverse effects, including physical dependency and withdrawal. Caffeine is not proposed to be restricted for high school-aged students. Given the practical realities and market for caffeinated beverages enjoyed by high school aged students, it was not deemed practical to restrict caffeinated beverages for this age group. However, the Department does request comments on this exception for high school students. This proposed provision may be found at § 210.11(l).

Beverages

In developing proposed standards for beverages sold in competition with school meals, the Department is proposing standards for allowable beverage types that are consistent with the IOM recommendations for elementary and middle school students, but which allow a greater variety of beverages for sale to high school students. Specifically, calorie-free, flavored and/or carbonated water, and low-calorie (less than 40 or 50 calories per 8 ounces) beverages are allowed for high school students, but not allowed for elementary or middle school students. This approach recognizes the wide range of beverages available to high school students in the broader marketplace and the increased independence such students have, relative to younger students, in making consumer choices. Given those circumstances, the Department considers it reasonable to provide high school students a broader range of choices, while still limiting those choices to those which are more nutrient dense and/or lower in calories than other options. Elementary and middle school students may develop healthier habits because of this limitation.

The proposed rule also specifies allowable beverages and maximum portion sizes for such beverages. The proposed beverage standards provide consistent sizes for each age group.

The proposed beverage requirements are:

Elementary School:

- Plain water (no size limit);
- Low fat milk, plain (not more than 8 fluid ounces);
- Non fat milk, plain or flavored (not more than 8 fluid ounces);
- Nutritionally equivalent milk alternatives as permitted by the school meal requirements (not more than 8 fluid ounces); and
- 100% fruit/vegetable juice (not more than 8 fluid ounces)

Middle School:

- Plain water (no size limit);
- Low fat milk, plain (not more than 12 fluid ounces);
- Non fat milk, plain or flavored (not more than 12 fluid ounces);
- Nutritionally equivalent milk alternatives as permitted by the school meal requirements (not more than 12 fluid ounces); and
- 100% fruit/vegetable juice (not more than 12 fluid ounces);

High School:

- Plain water (no size limit);
- Low fat milk, plain (not more than 12 fluid ounces);
- Non fat milk, plain or flavored (not more than 12 fluid ounces);
- Nutritionally equivalent milk alternatives as permitted by the school meal standards (not more than 12 fluid ounces);
- 100% fruit/vegetable juice (not more than 12 fluid ounces);
- Calorie-free, flavored and/or carbonated water (not more than 20 fluid ounces) allowed, but not in the meal service area during meal service periods;
- Other beverages (not more than 20 fluid ounces) that comply with the FDA requirement for bearing a ''calorie free'' claim of less than 5 kcals/serving allowed, but not in the meal service area during meal service periods; and
- Other beverages in ≤ 12 oz servings allowed, but not in the meal service area during the meal service periods. Two alternatives are proposed. The first (D1) would allow 40 calories per 8 ounce serving of beverages (or no more than 60 calories per 12 ounce serving of such beverages) for high school students. The second (D2) would allow 50 calories per 8 ounce serving of beverages (or no more than 75 calories per 12 ounce serving of such beverages) for high school students. The slightly higher calorie limit would allow a broader range sports drinks to be purchased.

The beverage standards proposed in this rule are consistent with most currently established voluntary standards regarding the types of beverages sold to students on campus

during the school day. However, the package/container sizes for 100% juice and milk as proposed in this rule are larger than those recommended by the IOM in its report on nutrition standards for food in schools (IOM did not recommend allowing any amount of other caloric beverages aside from juice and milk). The amounts of 100% juice and milk proposed for elementary and middle schools are also higher than the voluntary standards set by the Alliance for a Healthier Generation.

The American Academy of Pediatrics recommends limiting 100 percent juice for children 7 to 18 years old to 8 to 12 ounces per day. Under the interpretation of the new meal pattern requirements there is no juice limit per day but rather per week. The Dietary Guidelines Advisory Committee Report states that limited and inconsistent evidence suggests that for most children, intake of 100 percent fruit juice is not associated with increased fat, when consumed in amounts that are appropriate for age and energy needs of the child. The DGA 2010 recommends that most of one's fruit choices should be whole or cut-up fruit, rather than juice, for the benefits that dietary fiber provides.

Most children 9 years and older consume less than one cup of milk per day. While allowing package sizes for milk up to 12 ounces for secondary school students does contribute extra calories, it also provides children with needed calcium, vitamin D and potassium and could help move children's consumption of Dairy foods closer to dietary recommendations.

As indicated previously, the rationale behind the approach taken in this proposed rule is the practical recognition of current packaging practices.

However, the Department realizes that there would be an increase in calories and added sugars incurred by allowing larger package sizes and welcomes public comments on the proposed beverage amounts.

These proposed provisions are found in § 210.11(b)(2) and § 210.11(m).

Fundraisers

School-sponsored fundraisers are recognized as reasonable enhancements to the school community as well as a method of financing some important school-sanctioned activities for students. The sale of food items that meet the proposed nutrition requirements (as well as the sale of non-food items) at fundraisers would not be limited in any way under the proposed rule. In addition, the proposed standards would not apply to food sold during non-school hours, weekends and off-campus fundraising events such as concessions during after-school sporting events. Further, the proposed standards would not apply to food or beverages sold on school grounds, during school hours at ''a limited number'' of school fundraisers. The determination of what constitutes ''a limited number'' will be decided by the state agencies under one of two alternative approaches. It is expected that state agencies will ensure that the frequency of such fundraisers on school grounds, during school hours does not reach a level to impair the effectiveness of nutrition requirements described in this rule. With respect to other non-exempted fundraising activities during the school day (including fundraising through vending machines, school stores, snack bars, a la carte sales, and other similar activities as determined by the Secretary), the food and beverage items sold must meet the proposed nutrition standards for competitive foods.

The Department is especially interested in obtaining input from the public on this particular provision. This proposed rule includes two alternative approaches to exemptions to the competitive food standards for school-sponsored fundraisers, as well as a request for other suggestions from commenters. In addition, since the Department does not have detailed data regarding fundraising activities at schools, especially with regard to the types, frequency, restrictions during meal time, etc., that have been established by schools, commenters may also wish to provide input in this area.

The first alternative is to allow State agencies the discretion to establish limitations on the number of exempt fundraisers that may be held during the school year. The second alternative is to allow State agencies to set exempt fundraising frequency standards, subject to USDA approval.

Suggested timeframes from commenters for the conduct of exempt fundraisers in schools are also welcome. The two alternative approaches discussed above are included in § 210.11(b)(5).

Regardless of the approach ultimately adopted by the Department in a final rule, it is important to note that individual States and/or school districts may implement more restrictive competitive food standards, including those related to the frequency with which exempt fundraisers may be held in schools.

As stated above, this rule does not propose standards for frequency of school-sponsored fundraisers that provide foods or beverages that meet the nutrition standards for competitive foods. The limitations in this rule would deal only with those school-sponsored fundraisers that are exempt from the competitive food nutrition standards. However, the proposal does prohibit the sale of specially exempted fundraiser foods and beverages during the school meal service so as not to compete with the school meal.

Other Proposed Standards

Accompaniments

To reduce the added sodium, fats and sugars in food available and served to students during the school day, it is proposed that the use of accompaniments be limited when food is sold to students in school. All accompaniments shall be pre-portioned and must be included in the nutrient profile as a part of the item served as well as meet all of the proposed standards. For example, dressings served with salads, butter or jelly on muffins, cream cheese with a bagel and garnishes shall be pre-portioned in amounts appropriate to ensure that the competitive food standards are met and shall be included in the nutrient profile of the item. The Department seeks comment on the impact that such a requirement may have on competitive food service in schools. This proposed provision is found in § 210.11(n).

Foods of Minimal Nutritional Value (FMNV)

This rule requires that all food and beverages available and served to students meet the specific standards for competitive foods outlined in this proposed rule. It is no longer necessary, therefore, to retain the more narrowly defined standards for food of minimal nutritional value included in the current regulations. Accordingly, the proposal would remove the definition of ''food of minimal nutritional value'' from 7 CFR part 210 and the definition of ''foods of minimal nutritional value'' from 7 CFR part 220, and make other conforming changes in both of these parts.

Summary of General Impacts of the Proposed Competitive Food Standards

As proposed in this rule, all food and beverage products are subject to each of the proposed competitive food standards, with some specific exemptions for food items to be encouraged. Many existing products, particularly those encouraged by the Dietary Guidelines, would be available without restriction under these standards. Many products that would not meet these standards under current product formulations and package sizes

could meet the standards with changes to product packaging size or product formulation. In some cases, necessary formulation changes would be relatively modest (e.g., adding or increasing whole grains in certain products), while in others, more significant changes would be required in order for a product to meet the competitive food standards. Some products may also be able to meet the standards by modifying packaging; for example, reducing existing single-serving packages to meet calorie or sodium requirements. Finally, there are some products, such as those in which sugar is the primary ingredient, for which it is unlikely that changes could modify the product in a way that would allow the product to comply with the competitive food standards. Such products include soft drinks that contain sugar and/or caffeine (proposed to be restricted for elementary and middle school students), candy and other confections, whole milk, jams, jellies, certain dessert items as well as certain fruit products that contain added sugars.

Snack foods such as chips and other bagged snack items would most likely be most impacted by the proposed sodium, calorie and fat standards, as well as the requirement that the item contain 50% or more whole grains, or have its first ingredient be a whole grain or other food to encourage as recommended by the DGA. As currently packaged, many baked tortilla chips, reduced fat corn chips and baked potato chips would meet the proposed standards and would be allowed. However, other snack products as currently packaged and formulated, such as regular corn chips, cheese puffs and many flavored popcorn snack items would not meet the standards.

Grain based dessert items such as cookies, snack bars, pastries and cakes would likely be most impacted by the proposed grain, sugar, fat, and calorie standards. As currently packaged, many low-fat granola bars could be sold, while many cereal bars, cookies, and snack cakes currently contain too much sugar to meet the proposed standards. A number of other popular products, such as certain sweet snack crackers, may be able to meet the standards if such items are reformulated to increase the amount of whole grains they contain.

Fruit-based products with relatively limited amounts of added sugar or other products would be allowed. For example, some frozen fruit treats have water and fruit as their first ingredients and are below the sugar limits. However, many other fruit snacks and fruit beverages that have added ingredients would be limited by sugar and calorie limits. For example, nearly half of the calories contained in most gummy fruit snack and fruit roll-up type products are derived from sugar. Similarly, many frozen fruit popsicles or sorbet products have water and sugar as their first ingredients and, as such, would not meet the proposed standards.

Dairy snack products are most impacted by the proposed fat, sugar, and sodium standards included in this rule. Some frozen dairy products, puddings, etc, as currently formulated would meet the proposed standards, while others would not. However, most low fat/nonfat yogurt products will meet the standards due to the total sugar exemption proposed in this rule.

In addition, low fat cheeses are proposed to be exempt from the fat standards, and many lower-sodium cheese products would qualify.

Beverages, other than milk, would be limited by calorie and caffeine standards. While regular soda would not be allowed, diet sodas would be permitted in high schools in 20 oz. containers. Zero calorie versions of sport drinks or fitness waters would also be allowed in high schools in 20 oz. portions, as would 12 oz. portions of sports drinks or other beverages with 40 calories per 8 oz. (Alternative D1) or 50 calories per 8 oz (Alternative D2)In evaluating the impacts of this proposed rule, the Department has also considered the impacts of these changes on the vendors that supply food items, including competitive food items, to schools for sale outside of the Federal school meal programs. The proposed rule may require a number of SFA's to significantly change the food items that are offered for sale on school grounds. However, from the date of publication of this proposed rule, SFA's and their vendors will have significant time to prepare for this transition. Further, while it is anticipated that this regulation will eventually improve the nutritional options offered to students, the Department estimates overall direct impact on the sales of food items in the U.S. would be very limited. Currently, the Department estimates that the sale of competitive foods in schools may represent less than one percent of all food shipments from U.S. food manufacturers. Notwithstanding this initial analysis, the Department is specifically seeking comments on impacts of the proposed rule on the U.S. food industry, including small businesses, beyond what is discussed above and on ways these impacts can be minimized consistent with the purposes of section 10 of the Child Nutrition Act of 1966.

Recordkeeping and Monitoring Requirements

This rule proposes to impose recordkeeping requirements on local educational agencies regarding the implementation of these proposed nutrition standards in areas under their jurisdiction that are outside of the control of the school food service operation. The competitive food nutrition standards apply throughout the school campus and apply to all food available for sale to students outside of the reimbursable school meals at any venue available to students for the purchase of food, such as school stores, vending machines, concession stands, fundraising events held on campus, snack bars, etc. It is the responsibility of school food authorities to ensure and document that foods sold by the school food service to students during the meal service periods in meal service areas meet the proposed competitive food standards. However, since these competitive food standards apply to foods sold throughout all of the venues available in the schools (other than reimbursable meals), the responsibility for demonstrating compliance with these competitive food requirements must also include the local educational agency, as defined in § 210.2 of the current NSLP regulations, as well. This proposed rule provides that local educational agencies shall require that, at a minimum, receipts, nutrition labels or product specifications be maintained by those designated as responsible for competitive food service at the various venues in the schools in order to ensure and document compliance with the competitive food requirements for the foods and beverages available to be sold to students at these venues. FNS will provide technical assistance and guidance as necessary to State agencies and local educational agencies in this regard. This proposed provision may be found at § 210.11(b)(3).

It is proposed that State agencies be responsible for monitoring compliance with the requirements of the competitive food nutrition standards through a review of local educational agency records documenting compliance with these requirements. This requirement has been included in § 210.18(h)(7) as part of the general areas of State agency administrative review responsibilities. As with other program violations, if a State agency determines during an administrative review that violations of the competitive food standards have occurred, corrective action plans would be required to be submitted to the State agency by the local educational agency and school

food authority. FNS will consider any further actions that may be associated with continued noncompliance with competitive food standards, among other program violations, in a forthcoming proposed rule implementing Section 303 of the HHFKA, *Fines for Violating Program Requirements.*

Procedural Matters

Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This proposed rule has been designated an ''economically significant regulatory action'' under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

Regulatory Flexibility Analysis

This rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act of 1980 (5 U.S.C.601–612). It has been certified that this rule will have a significant economic impact on a substantial number of small entities.

The requirements established by this proposed rule will apply to school districts, which meet the definitions of ''small governmental jurisdiction'' and ''small entity'' in the Regulatory Flexibility Act. An Initial Regulatory Flexibility Act analysis is included in the preamble.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under section 202 of the UMRA, the Department generally must prepare a written statement, including a cost/benefit analysis, for proposed and final rules with Federal mandates that may result in expenditures to State, local, or Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. When such a statement is needed for a rule, section 205 of the UMRA generally requires the Department to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, more cost-effective or least burdensome alternative that achieves the objectives of the rule. This rule does not contain Federal mandates (under the regulatory provisions of Title II of the UMRA) that impose costs on State, local, or Tribal governments or to the private sector of $100 million or more in any one year. This rule is, therefore, not subject to the requirements of sections 202 and 205 of the UMRA.

Executive Order 12372

The NSLP is listed in the Catalog of Federal Domestic Assistance under No. 10.555. The SBP is listed in the Catalog of Federal Domestic Assistance under No. 10.553. For the reasons set forth in the final rule in 7 CFR part 3015, Subpart V and related notice (48 FR 29115, June 24, 1983), these programs are included in the scope of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

Executive Order 13132

Executive Order 13132 requires Federal agencies to consider the impact of their regulatory actions on State and local governments. Where such actions have federalism implications, agencies are directed to provide a statement for inclusion in the preamble to the regulations describing the agency's considerations in terms of the three categories called for under section (6)(b)(2)(B) of Executive Order 13132. USDA has considered the impact of this rule on State and local governments and has determined that this rule does not have federalism implications. This rule does not impose substantial or direct compliance costs on State and local governments. Therefore, under Section 6(b) of the Executive Order, a federalism summary impact statement is not required.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is intended to have preemptive effect with respect to any State or local laws, regulations or policies which conflict with its provisions or which would otherwise impede its full implementation. This rule is not intended to have retroactive effect unless specified in the **DATES** section of the final rule. Prior to any judicial challenge to the provisions of this rule or the application of its provisions, all applicable administrative procedures must be exhausted.

Civil Rights Impact Analysis

FNS has reviewed this rule in accordance with Departmental Regulations 4300–4, ''Civil Rights Impact Analysis,'' and 1512–1, ''Regulatory Decision Making Requirements.'' After a careful review of the rule's intent and provisions, FNS has determined that this rule is not intended to limit or reduce in any way the ability of protected classes of individuals to receive benefits on the basis of their race, color, national origin, sex, age or disability nor is it intended to have a differential impact on minority owned or operated business establishments and woman-owned or operated business establishments that participate in the Child Nutrition Programs.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. Chap. 35; see 5 CFR 1320), requires that the Office of Management and Budget (OMB) approve all collections of information by a Federal agency from the public before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current, valid OMB control number. This proposal would require a new collection. The new provisions in this rule which would increase burden hours, affect the information collection requirements that will be merged into the National School Lunch Program, OMB Control Number #0584–0006, expiration date 5/31/2012. The current collection burden inventory for the National School Lunch Program is 12,181,012. These changes are contingent upon OMB approval under the Paperwork Reduction Act of 1995. When the information collection requirements have been approved, FNS will publish a separate action in the **Federal Register** announcing OMB's approval.

Comments on the information collection in this proposed rule must be received by April 9, 2013.

Send comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for FNS, Washington, DC 20503. Please also send a copy of your comments to Jon Garcia, Program Analysis and Monitoring Branch, Child Nutrition Division, 3101 Park Center Drive, Alexandria, VA 22302. For further information, or for copies of the information collection requirements, please contact Lynn Rodgers-Kuperman at the address indicated above. Comments are invited on: (1) Whether the proposed collection of information is necessary for the

proper performance of the Agency's functions, including whether the information will have practical utility; (2) the accuracy of the Agency's estimate of the proposed information collection burden, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this request for comments will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Title: National School Lunch Program and School Breakfast Program: Nutrition Standards for All Foods Sold in School as Required by the Healthy, Hunger-Free Kids Act of 2010.

OMB Number: 0584–NEW

Expiration Date: Not Yet Determined

Type of Request: New Collection

Abstract: This rule sets forth proposed provisions to implement sections 203 and 208 of Public Law 111–296, the Healthy, Hunger-Free Kids Act of 2010 (HHFKA), enacted December 13, 2010.

Section 203 of the HHFKA amends section 9(a) of the Richard B. Russell National School Lunch Act by requiring that schools participating in the NSLP make potable water available to children at no charge in the place where lunches are served during the meal service. This is a nondiscretionary requirement of the HHFKA, effective October 1, 2010.

Section 208 of the HHFKA amends Section 10 of the Child Nutrition Act of 1966 (42 U.S.C. 1779) to give the Secretary of Agriculture new authority to establish nutrition standards for all foods and beverages sold outside of the Federal school meal programs on the campus of schools during the school day. The CNA as amended by the HHFKA requires that the Secretary promulgate proposed regulations to establish science-based nutrition standards for foods sold in schools other than those foods provided under the CNA and NSLA.

Those participating in the SBP also participate in the NSLP, thus the burden associated with the SBP will be carried in the NSLP. The average burden per record and the annual burden hours for recordkeeping are explained below and summarized in the charts which follow. In addition, provisions under sections 203 and 208 of the HHFKA do not contain new reporting requirements.

Recordkeepers for this Proposed Rule: State Agencies (SAs) (57) and School Food Authorities (SFAs) (20,858) and Schools (101,747)

Estimated Number of Recordkeepers for this Proposed Rule: 122,662

Estimated Number of Records per Recordkeeper for this Proposed Rule: 1.033457

Estimated Total Annual Records: 126,766

Estimated Average Burden Hours per Record: 7.31217

Estimated Total Annual Burden Hours on Recordkeepers for this Proposed Rule: 926,935

ESTIMATED ANNUAL BURDEN FOR 0584—NEW, NUTRITION STANDARDS FOR ALL FOODS SOLD IN SCHOOL

[7 CFR 210]

	Section	Estimated number of record-keepers	Records per record-keeper	Average annual records	Average burden per record	Annual burden hours
Recordkeeping						
SAs shall ensure that the LEA complies with the nutrition standards for competitive foods and retains documentation demonstrating compliance.	7 CFR 210.18(h)(7)	57	73	4,161	0.25	1,040
LEAs and SFAs shall be responsible for maintaining records documenting compliance with the competitive food standards.	7 CFR 210.11(b)(3)	20,858	1	20,858	20	417,160
Organizations responsible for competitive food service at various venues in schools shall maintain records.	7 CFR 210.11(b)(3)	101,747	1	101,747	5	508,735
Total Recordkeeping for Proposed Rule.	.....	122,662	.....	126,766	7.3122	926,935

7 CFR 210.15 and 7 CFR 210.20 require that, to participate in the National School Lunch Program, school food authorities and State agencies must maintain records to demonstrate compliance with Program requirements. 7 CFR 210.23 further requires that State agencies and school food authorities maintain records for a period of 3 years.

SUMMARY OF BURDEN (OMB #0584–NEW)

Total No. Recordkeepers	122,662
Average No. Records per Recordkeeper	1.033457
Total Annual Records	126,766
Average Hours per Record	7.31217
Total Burden Hours for Part 210 with Proposed Rule	13,107,947
Current OMB Inventory for Part 210	12,181,012
Difference (New Burden Requested with Proposed Rule)	926,935

E-Government Act Compliance

The Food and Nutrition Service is committed to complying with the E–Government Act of 2002, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services and for other purposes.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the federal government and Indian Tribes. In Spring 2011, FNS offered opportunities for consultation with Tribal officials or their designees to discuss the impact of the Healthy, Hunger-Free Kids Act of 2010 on tribes or Indian Tribal governments. The consultation sessions were coordinated by FNS and held on the following dates and locations:

1. HHFKA Webinar & Conference Call—April 12, 2011

2. Mountain Plains—HHFKA Consultation, Rapid City, SD—March 23, 2011

3. HHFKA Webinar & Conference Call—June, 22, 2011

4. Tribal Self-Governance Annual Conference in Palm Springs, CA—May 2, 2011

5. National Congress of American Indians Mid-Year Conference, Milwaukee, WI—June 14, 2011

The five consultation sessions in total provided the opportunity to address Tribal concerns related to school meals. There were no comments about this regulation during any of the aforementioned Tribal consultation sessions.

Reports from these consultations are part of the USDA annual reporting on Tribal consultation and collaboration. FNS will respond in a timely and meaningful manner to Tribal government requests for consultation concerning this rule. Currently, FNS provides regularly scheduled quarterly consultation sessions as a venue for collaborative conversations with Tribal officials or their designees.

Regulatory Impact Analysis Summary

As required for all rules that have been designated as significant by the Office of Management and Budget, a Regulatory Impact Analysis (RIA) was developed for this proposal. A summary is presented below. The full RIA is published as part of the Docket on *www.regulations.gov*.

Need for Action

The proposed rule responds to two provisions of the Healthy, Hunger-Free Kids Act of 2010. Section 208 of HHFKA amended Section 10 of the Child Nutrition Act of 1966 to require the Secretary to establish science-based nutrition standards for all foods sold in schools during the school day.

Benefits

The primary purpose of the proposed rule is to ensure that nutrition standards for competitive foods are consistent with the most recent DGA recommendations, effectively holding competitive foods to the same standards as the rest of the foods sold at school during the school day. These standards, combined with recent improvements in school meals, will help promote diets that contribute to students' long-term health and well-being. And they will support parents' efforts to promote healthy choices for children at home and at school.

Obesity has become a major public health concern in the U.S., with one-third of U.S. children and adolescents now considered overweight or obese (Beydoun and Wang 2011 [4]), with current childhood obesity rates four times higher in children ages six to 11 than they were in the early 1960s (19 vs. 4 percent), and three times higher (17 vs. 5 percent) for adolescents ages 12 to 19.[5] Research focused specifically on the effects of obesity in children indicates that obese children feel they are less capable, both socially and athletically, less attractive, and less worthwhile than their non-obese counterparts.[6] Further, there are direct economic costs due to childhood obesity: $237.6 million (in 2005 dollars) in inpatient costs [7] and annual prescription drug, emergency room, and outpatient costs of $14.1 billion.[8]

Because the factors that contribute both to overall food consumption and to obesity are so complex, it is not possible to define a level of disease or cost reduction expected to result from implementation of the rule. There is some evidence, however, that competitive food standards can improve children's dietary quality:

- Taber, Chriqui, and Chaloupka (2012 [9]) concluded that California high school students consumed fewer calories, less fat, and less sugar at school than students in other States. Their analysis ''suggested that California students did not compensate for consuming less within school by consuming more elsewhere'' (p. 455).
- Schwartz, Novak, and Fiore, (2009 [10]) determined that healthier competitive food standards decreased student consumption of low nutrition items with no compensating increase at home.
- Researchers at Healthy Eating Research and Bridging the Gap found that ''[t]he best evidence available indicates that policies on snack foods and beverages sold in school impact children's diets and their risk for obesity. Strong policies that prohibit or restrict the sale of unhealthy competitive foods and drinks in schools are associated with lower proportions of overweight or obese students, or lower rates of increase in student BMI'' (Healthy Eating Research and Bridging the Gap, 2012, p. 3 [11]).

[4] Beydoun, M.A. and Y. Wang. 2011. Socio-demographic disparities in distribution shifts over time in various adiposity measures among American children and adolescents: What changes in prevalence rates could not reveal. *International Journal of Pediatric Obesity,* 6:21–35. As cited in Food Labeling: Calorie Labeling of Articles of Food in Vending Machines NPRM. 2011. Preliminary Regulatory Impact Analysis, Docket No. FDA–2011–F–0171.

[5] Ogden et al. *Prevalence of Obesity Among Children and Adolescents: United States, Trends 1963–1965 Through 2007–2008.* CDC–NHCS, NCHS Health E–Stat, June 2010. On the web at *http://www.cdc.gov/nchs/data/hestat/obesity_child_07_08/obesity_child_07_08.htm.*

[6] Riazi, A., S. Shakoor, I. Dundas, C. Eiser, and S.A. McKenzie. 2010. Health-related quality of life in a clinical sample of obese children and adolescents. Health and Quality of Life Outcomes, 8:134–139.Samuels & Associates. 2006. Competitive Foods. Policy Brief prepared by Samuels & Associates for The California Endowment and Robert Wood Johnson Foundation. Available at: *http://www.healthyeatingactivecommunities.org/downloads/*

[7] Trasande, L., Y. Liu, G. Fryer, and M. Weitzman. 2009. Trends: Effects of Childhood Obesity on Hospital Care and Costs, 1999–2005. *Health Affairs,* 28:w751-w760.

[8] Cawley, J. 2010. The Economics of Childhood Obesity. *Health Affairs,* 29:364–371. As cited in Food Labeling: Calorie Labeling of Articles of Food in Vending Machines NPRM. 2011. Preliminary Regulatory Impact Analysis, Docket No. FDA–2011–F–0171.

[9] Taber, D.R., J.F. Chriqui, and F. J. Chaloupka. 2012. Differences in Nutrient Intake Associated With State Laws Regarding Fat, Sugar, and Caloric Content of Competitive Foods. *Archives of Pediatric & Adolescent Medicine,* 166:452–458.

[10] Schwartz, M.B., S.A. Novak, and S.S. Fiore. 2009. The Impact of Removing Snacks of Low Nutritional Value from Middle Schools. *Health Education & Behavior,* 36:999–1011.

[11] Healthy Eating Research and Bridging the Gap. 2012. Influence of Competitive Food and Beverage Policies on Children's Diets and Childhood Obesity.

A recent, comprehensive, and groundbreaking assessment of the evidence on the importance of competitive food standards conducted by the Pew Health Group concluded that a national competitive foods policy would increase student exposure to healthier foods, decrease exposure to less healthy foods, and would also likely improve the mix of foods that students purchase and consume at school. Researchers concluded that these kinds of changes in food exposure and consumption at school are important influences on the overall quality of children's diets.

Although nutrition standards for foods sold at school alone may not be a determining factor in children's overall diets, they are critical to providing children with healthy food options throughout the entire school day. Thus, these standards will help to ensure that the school nutrition environment does all that it can to promote healthy choices, and help to prevent diet-related health problems. Ancillary benefits could derive from the fact that improving the nutritional value of competitive foods may reinforce school-based nutrition education and promotion efforts and contribute significantly to the overall effectiveness of the school nutrition environment in promoting healthful food and physical activity choices.[12]

Costs

The proposed rule requires schools to improve the nutritional quality of foods offered for sale to students outside of the Federal school lunch and school breakfast programs. The new standards apply to foods sold à la carte, in school stores or vending machines, and, pending provisions of the final rule regarding occasional exemptions, through in-school fundraisers sponsored by students, parents, or other school-affiliated groups. Upon implementation of the rule, students will face new food choices from these sources. The new choices will meet standards for fat, saturated fat, sugar, and sodium, and have whole grains, low fat dairy, fruits, vegetables, or protein foods as their main ingredients. Our analysis examines a range of possible behavioral responses of students and schools to these changes. To estimate potential effects on school revenue, we look to the experience of school districts that have adopted or piloted competitive food reforms in recent years.

The practice of selling foods in competition with Federally reimbursable program meals and snacks is widespread. In SY 2004–2005, 82 percent of all schools—and 92 percent of middle and high schools—offered à la carte foods at lunch. Vending machines were available in 52 percent of all schools and 26 percent of elementary schools, 87 percent of middle schools, and 98 percent of high schools (Gordon, et al., 2007; Volume 1, pp 102–114).

The limited information available indicates that many schools have successfully introduced competitive food reforms with little or no loss of revenue and in a few cases, revenues from competitive foods increased after introducing healthier foods. In some of the schools that showed declines in competitive food revenues, losses from reduced sales were fully offset by increases in reimbursable meal revenue. In other schools, students responded favorably to the healthier options and competitive food revenue declined little or not at all.

But not all schools that adopted or piloted competitive food standards fared as well. Some of the same studies and reports that highlight school success stories note that other schools sustained some loss after implementing similar standards. While in some cases these were short-term losses, even in the long-term the competitive food revenue lost by those schools was not offset (at least not fully) by revenue gains from the reimbursable meal programs.

Our analysis examines the possible effects of the proposed rule on school revenues from competitive foods and the administrative costs of complying with the rule's competitive foods provisions. The analysis uses available data to construct model-based scenarios that different schools may experience in implementing the proposed rule. While these vary in their impact on overall school food revenue, each scenario's estimated impact is relatively small (+0.4 percent to −0.7 percent). In comparison, the regulations implementing the school food service revenue provisions of HHFKA would increase average overall school food revenue by roughly six percent. That said, the data behind the scenarios are insufficient to assess the frequency or probability of schools experiencing the impacts shown in each.

List of Subjects

7 CFR Part 210

Grant programs-education; Grant programs-health; Infants and children; Nutrition; Reporting and recordkeeping requirements; School breakfast and lunch programs; Surplus agricultural commodities.

7 CFR Part 220

Grant programs-education; Grant programs-health; Infants and children; Nutrition; Reporting and recordkeeping requirements; School breakfast and lunch programs.

Accordingly, for the reasons discussed in the preamble, 7 CFR parts 210 and 220 are proposed to be amended as follows:

PART 210—NATIONAL SCHOOL LUNCH PROGRAM

■ 1. The authority citation for 7 CFR part 210 continues to read as follows:

Authority: 42 U.S.C. 1751–1760, 1779.

■ 2. In § 210.1, revise the second sentence of paragraph (b) to read as follows:

§ 210.1 General purpose and scope.

* * * * *

(b) * * * It specifies Program responsibilities of State and local officials in the areas of program administration, preparation and service of nutritious lunches, the sale of competitive foods, payment of funds, use of program funds, program monitoring and reporting and recordkeeping requirements.

■ 3. In § 210.10, amend paragraphs (a)(1)(i) and (a)(1)(ii) by adding a new sentence at the end of the each paragraph.

The additions read as follows:

§ 210.10 Nutrition standards and menu planning approaches for lunches and requirements for afterschool snacks.

(a) * * *

(1) * * *

(i) * * * Schools shall make potable water available to children at no charge in the place where lunches are served during the meal service.

(ii) * * * Schools shall make potable water available to children at no charge in the place where afterschool snacks are served during the afterschool snack service.

* * * * *

■ (4) Revise § 210.11 to read as follows:

§ 210.11 Competitive food service and standards.

(a) *Definitions.* For the purpose of this section:

Available at *http://www.healthyeatingresearch.org/images/stories/her_research_briefs/Competitive_Foods_Issue_Brief_HER_BTG_7-2012.pdf.*

[12] Pew Health Group and Robert Wood Johnson Foundation. 2012. Heath Impact Assessment: National Nutrition Standards for Snack and a la Carte Foods and Beverages Sold in Schools. Available online: *http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Reports/KS%20HIA_FULL%20Report%20062212_WEB%20FINAL-v2.pdf.*

(1) *Competitive food* means all food and beverages other than meals reimbursed under programs authorized by the Richard B. Russell National School Lunch Act and the Child Nutrition Act of 1966 available for sale to students on the *School campus* during the *School day;*

(2) *School day* means, for the purpose of competitive food standards implementation, the period from the midnight before, to 30 minutes after the end of the official school day;

(3) *School campus* means, for the purpose of competitive food standards implementation, all areas of the property under the jurisdiction of the school that are accessible to students during the school day; and

(4) *Combination foods* means products that contain two or more components representing two or more of the recommended food groups: fruit, vegetable, dairy, protein or grains.

(b) *General requirements for competitive food.*

(1) State agencies and/or local educational agencies shall establish such policies and procedures as are necessary to ensure compliance with this section. State agencies and/or local educational agencies may impose additional restrictions on competitive foods, provided that they are not inconsistent with the requirements of this part.

(2) The sale of otherwise allowable calorie-free and low calorie, flavored and/or carbonated water as provided in paragraphs (m)(3)(vi), (m)(3)(vii), and (m)(3)(viii) of this section in food service areas during the meal service is prohibited.

(3) The local educational agency is responsible for the maintenance of records that document compliance with the nutrition standards for all competitive food available for sale to students in areas under its jurisdiction that are outside of the control of the school food authority responsible for the service of reimbursable school meals. School food authorities shall be responsible for maintaining records documenting compliance with these standards in meal service areas during meal service periods. The local educational agency shall be responsible for ensuring that organizations designated as responsible for food service at the various venues in the schools maintain records in order to ensure and document compliance with the nutrition requirements for the foods and beverages available to be sold to students at these venues during the school day as required by this part. At a minimum, such records shall include receipts, nutrition labels and/or product specifications for the items available for sale to students on the school campus during the school day.

(4) The nutrition standards for the sale of competitive food outlined in this section shall apply to competitive food for all programs authorized by the Richard B. Russell National School Lunch Act and the Child Nutrition Act of 1966 operating on the school campus during the school day.

(5) *Fundraiser restrictions.* Food and beverage items sold during the school day shall meet the nutrition standards for competitive food as required in this part. A special exemption shall be allowed for the sale of food and/or beverages that do not meet the competitive food nutrient standards as required in this section for the purpose of conducting a school-sponsored fundraiser. Such specially exempted fundraisers shall not take place more than:

(i) Alternative E1: the frequency specified by the State agency during such periods that schools are in session; or

(ii) Alternative E2: the frequency specified by the State agency and approved by USDA during such periods that schools are in session.

No specially exempted fundraiser foods or beverages may be sold in competition with school meals in the food service area during the meal service.

(c) *General nutrition standards for competitive foods.*

(1) At a minimum, all competitive food sold to students on the school campus during the school day must meet the nutrition standards specified in this section.

(2) To be allowable, a competitive food item must:

(i) Meet all of the competitive food nutrient standards as outlined in this section; and

(ii) Be a grain product that contains 50 percent or more whole grains by weight or have as the first ingredient a whole grain; or

(iii) Have as the first ingredient one of the non-grain main food groups: fruit, vegetable, dairy product or protein foods (meat, beans, poultry, seafood, eggs, nuts, seeds, etc.); or

(iv) Contain 10 percent of the Daily Value of a naturally occurring nutrient of public health concern (i.e., calcium, potassium, vitamin D or dietary fiber); or

(v) Be a combination food that contains ¼ cup of fruit or vegetable; and

(vi) If water is the first ingredient, the second ingredient must be one of the food items in (c)(2)(i), (c)(2)(ii), (c)(2)(iii), (c)(2)(iv) or (c)(2)(v) of this section.

(3) Exemptions.

(i) Alternative A1: All menu items provided as part of the NSLP or SBP reimbursable meal are exempt from these competitive food standards with the exception of the standards established for total fat and sugar, as specified. Grain based dessert products must meet all standards in order to be served. Such menu items shall be served in the same or smaller portion sizes as in the NSLP or SBP to be allowable; or

(ii) Alternative A2: All menu items provided as part of the NSLP or SBP reimbursable meal are exempt from these competitive food standards, with the exception of grain based dessert products which must meet all standards in order to be served. Such menu items shall be served in the same or smaller portion sizes as in the NSLP or SBP to be allowable, and must meet the timeframe exemptions specified in paragraph (4) of this section.

(4) *Exemptions.*

(i) Alternative B1: Exemptions to these nutrition requirements include side dishes (other than grain based dessert items) and entrée items sold a la carte in accordance with the requirements of paragraph (3)(ii) [Alternative A2] that are NSLP or SBP meal items that are offered on the same day as part of the reimbursable school meal. Such side dishes and entrée items must be offered in the same or smaller portion size as offered in the NSLP or SBP and meet the standards specific to the NSLP and SBP; or

(ii) Alternative B2: Exemptions to these nutrition requirements include side dishes (other than grain based dessert items) and entrée items sold a la carte in accordance with the requirements of paragraph (3)(ii) [Alternative A2] that are NSLP or SBP meal items that are offered within four operating days of their service as part of the reimbursable school meal during the current menu cycle. Such side dishes and entrée items must be offered in the same or smaller portion size as offered in the NSLP or SBP and meet the standards specific to the NSLP and SBP.

(d) *Fruits and vegetables.* Fresh, frozen and canned fruits and vegetables with no added ingredients except water or, in the case of fruit, packed in 100 percent fruit juice or extra light syrup, are exempt from the nutrient standards included in this section.

(e) *Grain products.* Grain products acceptable as a competitive food must include 50 percent or more whole grains by weight or have whole grain as the first ingredient. Grain products shall

meet all of the other nutrient standards included in this section.

(f) *Total fat.*

(1) The total fat content of a competitive food shall be not more than 35 percent of total calories from fat per portion as packaged.

(2) Exemptions to this requirement include the following:

(i) Reduced fat cheese is exempt from the total fat and saturated fat standard, but subject to the required trans fat, calorie, sugar and sodium standards;

(ii) Nuts and Seeds and Nut/Seed Butters are exempt from total fat standard, but subject to the required saturated fat, trans fat, calorie, sugar and sodium standards. This exemption does *not* extend to combination products that contain nuts, nut butters or seeds or seed butters with other ingredients such as peanut butter and crackers, trail mix, chocolate covered peanuts, etc.;

(iii) Products that consist of only dried fruit with nuts and/or seeds with no added nutritive sweeteners or fat are exempt from the total fat and sugar standards, but subject to the required saturated fat, trans fat, calorie and sodium standards; and

(iv) Seafood *with no added fat* is exempt from the total fat requirement in order to increase omega-3 fatty acids in diets as recommended by the 2010 DGA; but subject to the required sugar, saturated fat, trans fat, calorie and sodium standards.

(g) *Saturated fat.*

(1) The saturated fat content of a competitive food must be less than 10 percent of total calories per portion, except as specified in paragraph (g)(2).

(2) Reduced fat cheese is exempt from the total fat and saturated fat standards, but subject to the calorie, trans fat, sugar and sodium standards.

(h) *Trans fat.* The trans fat content of a competitive food must be zero grams trans fat per portion as packaged (not more than 0.5 grams per portion).

(i) *Total sugars.*

(1) Alternatives.

(i) Alternative C1: Total sugars contained in a competitive food item must be not more than 35 percent of *calories* per portion.

(ii) Alternative C2: Total sugars contained in a competitive food item must be not more that 35 percent of *weight* per portion.

(2) Exemptions to this requirement are:

(i) Dried whole fruits or vegetables; dried whole fruit or vegetable pieces; and dried dehydrated fruits or vegetables with no added nutritive sweeteners are exempt from the sugar standard, but subject to the calorie, total fat, saturated fat, trans fat and sodium standards;

(ii) Products that consist of only dried fruit with nuts and/or seeds with no added nutritive sweeteners or fat are exempt from the total fat and sugar standards, but subject to the calorie, trans fat, saturated fat and sodium standards; and

(iii) Flavored and unflavored nonfat and low-fat yogurt with no more than 30 grams of total sugars per 8 ounce serving is exempt from the sugar standard, but subject to the calorie, total fat, saturated fat, trans fat and sodium standards.

(j) *Calorie and sodium content for snack items and side dishes sold a la carte.* Snack items and side dishes sold a la carte other than those exempt from the competitive food nutrition standards as provided in § 210.11(c)(3) shall have not more than 200 calories and not more than 200 mg of sodium per portion as served, including the calories and sodium contained in any added accompaniments such as butter, cream cheese, salad dressing etc., and shall meet all of the other nutrient standards for non entrée items.

(k) *Calorie and sodium content for entrée items sold a la carte.*

(1) An entrée item is defined as an item that is either:

(i) A combination food of meat or meat alternate and whole grain-rich/bread; or

(ii) A combination food of vegetable or fruit and meat or meat alternate; or

(iii) A meat or meat alternate alone with the exception of yogurt, low-fat or reduced fat cheese, nuts, seeds and nut or seed butters.

(2) Entrée items sold a la carte other than those exempt from the competitive food nutrition standards as provided in § 210.11(c)(3) shall contain no more than 350 calories and 480 mg. of sodium per portion as served and meet all of the other nutrient standards in this section.

(l) *Caffeine.* Foods and beverages available to elementary and middle school-aged students shall be caffeine-free, with the exception of trace amounts of naturally occurring caffeine substances.

(m) *Beverages.*

(1) Allowable beverages for elementary school-aged students shall be limited to:

(i) Plain water (no size limit);

(ii) Low fat milk, plain (no more than 8 fluid ounces);

(iii) Non fat milk, plain or flavored (no more than 8 fluid ounces);

(iv) Nutritionally equivalent milk alternatives as permitted in § 210.10 and § 220.8 (no more than 8 fluid ounces); and

(v) 100 percent fruit/vegetable juice (no more than 8 fluid ounces).

(2) Allowable beverages for middle school-aged students shall be limited to:

(i) Plain water (no size limit);

(ii) Low fat milk, plain (no more than 12 fluid ounces);

(iii) Non fat milk, plain or flavored (no more than 12 fluid ounces);

(iv) Nutritionally equivalent milk alternatives as permitted in § 210.10 and § 220.8 (no more than 12 fluid ounces); and

(v) 100 percent fruit/vegetable juice (no more than 12 fluid ounces).

(3) Allowable beverages for high school-aged students shall be limited to:

(i) Plain water (no size limit);

(ii) Low fat milk, plain (no more than 12 fluid ounces);

(iii) Non fat milk, plain or flavored (no more than 12 fluid ounces);

(iv) Nutritionally equivalent milk alternatives as permitted in § 210.10 and § 220.8 (no more than 12 fluid ounces);

(v) 100 percent fruit/vegetable juice (no more than 12 fluid ounces);

(vi) Calorie-free, flavored and/or carbonated water (no more than 20 fluid ounces), except that such beverages shall not be available or served to students in the food service area during the meal service period;

(vii) No more than 20 fluid ounce servings of other beverages that comply with the Food and Drug Administration requirement for bearing a ''calorie free'' claim of less than 5 kcals/serving, except that such beverages shall not be available or served to students in the food service area during the meal service period; and

(viii) Alternative D1: No more than 12 fluid ounce servings of other beverages that contain no more than 40 calories per 8 fluid ounce serving or 60 calories per 12 fluid ounce serving, except that such beverages shall not be available or served to students in the food service area during the meal service period; or

(ix) Alternative D2: No more than 12 fluid ounce servings of other beverages that contain no more than 50 calories per 8 fluid ounce serving or 75 calories per 12 ounce serving, except that such beverages shall not be available or served to students in the food service area during the meal service period.

(n) *Accompaniments.* The use of accompaniments shall be limited when competitive food is sold to students in school. All accompaniments to a competitive food item shall be pre-portioned and the ingredients of such accompaniments must be included in the nutrient profile as a part of the food item served and shall meet all of the nutritional standards for competitive food as required in this section.

■ 5. In § 210.18, a new paragraph (h)(7) is added to read as follows:

§ 210.18 Administrative reviews.

* * * * *

(h) * * *

(7) *Compliance with competitive food standards.* The State agency shall ensure that the local educational agency complies with the nutrition standards for competitive foods and retains documentation demonstrating compliance with the competitive food service and standards outlined in § 210.11.

■ 6. Appendix B to Part 210 is removed and reserved.

PART 220—SCHOOL BREAKFAST PROGRAM

■ 1. The authority citation for 7 CFR part 220 continues to read as follows:

Authority: 42 U.S.C. 1773, 1779, unless otherwise noted.

■ 2. In § 220.2,

(a) The definition of ''Foods of minimal nutritional value'' is removed; and

(b) The definition of ''Competitive foods'' is removed.

■ 3. Section 220.12 is revised as follows:

§ 220.12 Competitive food services.

Competitive food services shall comply with the requirements specified in § 210.11 of this chapter.

■ 4. Appendix B to Part 220 is removed and reserved.

Dated: February 1, 2013.

Kevin W. Concannon,

Under Secretary, Food, Nutrition, and Consumer Services.

Note: The following appendix will not appear in the Code of Federal Regulations:

Initial Regulatory Flexibility Analysis—Proposed Rule

National School Lunch Program and School Breakfast Program: Nutrition Standards for All Foods Sold in School as Required by the Healthy, Hunger-Free Kids Act of 2010

Agency: Food and Nutrition Service, USDA.

Background: The Regulatory Flexibility Act (RFA) requires agencies to consider the impact of their rules on small entities and to evaluate alternatives that would accomplish the same objectives without undue burden when the rules impose a significant economic impact on a substantial number of small entities. Inherent in the RFA is the desire to remove barriers to competition and encourage consideration of ways to tailor regulations to the size of the regulated entities.

The RFA does not require that agencies necessarily minimize a rule's impact on small entities if there are significant, legal, policy, factual, or other reasons for the rule's impacts. The RFA requires only that agencies determine, to the extent feasible, the rule's economic impact on small entities, explore regulatory alternatives for reducing any significant economic impact on a substantial number of such entities, and explain the reasons for their regulatory choices.

Reasons That Action Is Being Considered: This rule sets forth proposed provisions to implement section 208 of Public Law 111–296, the Healthy, Hunger-Free Kids Act of 2010 (HHFKA). Section 208 amends Section 10 of the Child Nutrition Act of 1966 (42 U.S.C. 1779) (CNA) to give the Secretary of Agriculture new authority to establish science-based nutrition standards for all foods and beverages sold outside of the Federal child nutrition programs on the school campus during the school day. The Act also specifies that the nutrition standards shall apply to all foods sold (a) outside the school meal programs; (b) on the school campus; and (c) at any time during the school day.

Objectives of, and Legal Basis for, the Proposed Rule: As stated above, the legal basis for the proposed rule are the amendments made to the CNA by HHFKA. The objectives of this rule are to establish nutrition standards for all foods sold to students in schools other than meals served through child nutrition programs authorized under the NSLA or the CNA and to improve the health and well being of the Nation's school-aged children.

Number of Small Entities to Which the Proposed Rule Will Apply: This proposed rule directly regulates the 55 State education agencies and 2 State Departments of Agriculture that operate the NSLP pursuant to agreements with USDA's Food and Nutrition Service. In turn, its provisions apply to school districts, school food authorities, schools and others that prepare and sell foods other than those provided as reimbursable school lunches and breakfasts (such as à la carte food sales, vending machines, or other competitive food venues). While State agencies are not considered small entities as State populations exceed the 50,000 threshold for a small government jurisdiction, many of the service-providing institutions that work with them to implement the program do meet definitions of small entities:

- Nearly 101,000 schools and residential child care institutions (RCCIs) participate in NSLP. These include more than 90,000 public schools, 6,000 private schools, and about 5,000 RCCIs. A majority of those institutions also provide competitive foods through à la carte menus, vending, school stores, snack bars, fundraisers, or some combination of venues. Within individual schools, a variety of school groups (e.g., student clubs, parent teacher organizations, or parent ''booster'' organizations supporting activities such as sports, music, and enrichment activities) earn revenue from competitive foods.
- School Food Authorities (SFAs) earn competitive food revenues primarily through à la carte sales, but may also earn revenues from vending machine sales, school stores, snack bars, and other outlets.
- Manufacturers, wholesalers, and distributors, including vending machine operators, are not regulated by the proposed rule, but are indirectly affected. Of this group, vending operators with machines in primary and secondary schools may be the most affected. Vending businesses tend to have few employees; 76 percent of companies that operated for the entire year in 2007 employed fewer than 10 people.[13] Vending machines in primary and secondary schools make up just two percent of vending industry sales.[14]
- Food service management companies (FSMCs) that prepare school meals or menus under contract to SFAs may be indirectly affected by the proposed rule in that they may also prepare foods for the á la carte menu. Thirteen percent of public school SFAs contracted with FSMCs in school year (SY) 2004–2005.[15] Of 23,000 food service contractors that operated for the full year in 2007, 86 percent employed fewer than 100 workers.[16]

Projected Reporting, Recordkeeping and Other Compliance Requirements: The analysis below covers only those organizations impacted by the proposed rule that were determined to be small entities.

School Food Authorities and Other School Groups

An estimated 95 percent of competitive school food sales accrue to SFAs; the remaining five percent accrues to other school groups such as student clubs, parent teacher organizations, or parent ''booster'' organizations. If SFAs, other school groups, and the food industry are able to satisfy current student demand for competitive foods with new options that meet the proposed rule standards, then there may be no change in competitive food sales or competitive food revenue. And although the evidence base is limited, it suggests that many SFAs and other school groups have successfully introduced competitive food reforms with little or no loss of revenue, and in a few cases, revenues from competitive food sales have increased after introducing healthier foods. In some cases, decreases in competitive food sales have been offset by increases in school meal participation. In other cases, schools have experienced a decline in overall school food revenue.

The available data do not allow us to estimate the potential school revenue effect with any certainty. Instead, we have prepared

[13] Vending machine operators are described by ''NAICS'' code 454210. The code does not account for all vending machine businesses and data is not available to assess the proportion of vending machine businesses in schools. The statistics by establishment size are from the U.S. Census Bureau, 2007 Economic Census. Table 2, ''Employment Size of Establishments for the U.S.'' on *http://www.census.gov/econ/industry/ec07/a454210.htm.*

[14] The vending industry estimates that primary and secondary schools accounted for 2.2 percent ($1 billion out of $45.6 billion) of total vending machine sales in 2008. Census of the Industry 2009, Vending Times, *http://www.vendingtimes.com/Media/Sites-AdministratorsSiteNavigation/VendingTimes_Census2009.pdf.*

[15] U.S. Department of Agriculture, Food and Nutrition Service, Office of Research, Nutrition and Analysis, School Nutrition Dietary Assessment Study-III, Vol. I, 2007, p. 34 *http://www.fns.usda.gov/ora/MENU/Published/CNP/FILES/SNDAIII–Vol1.pdf.*

[16] Census Bureau, 2007 Economic Census, NAICS 72231. Table 2, ''Employment Size of Establishments for the U.S.'' on *http://www.census.gov/econ/industry/ec07/a72231.htm.*

a series of estimates that represent a range of plausible outcomes given the variety of experiences observed in several case studies. At one end of this range, we calculate that a four percent increase in competitive food revenues would result in a +0.4 percent increase in school food revenue over five years. At the other end of the range, we calculate that the standards in the proposed rule could reduce competitive food revenue by an estimated 4.8 percent, resulting in an overall decrease in school food revenues of −0.7 percent over five years. (Additional detail is provided in the Regulatory Impact Analysis for this rule.)

Case studies that consider the impacts of competitive food nutrition standards on SFA revenues find that reductions in competitive food revenue were often fully offset by increases in reimbursable meal revenue as students redirected their demand for competitive foods to the reimbursable school meal programs. In other instances, the lost competitive food revenue was not offset (at least not fully) by revenue gains from the reimbursable meal programs. Most SFAs have a number of options and some flexibility within available revenue streams and operations that can help minimize lost revenue. For example, about half of all SFA revenues are from Federal payments for reimbursable meals. SFAs can increase revenues to the extent that schools successfully encourage greater meal participation. In addition, the revenue impacts presented here are from a baseline that increased substantially at the start of SY 2011–2012, on implementation of interim final regulations for Sections 205 and 206 of HHFKA. These provisions will ensure that the revenue from competitive food sales is aligned with their cost.[17] The requirements of Section 206 are estimated to increase competitive food revenue by 35 percent, while the scenarios presented here anticipate a competitive food revenue loss of no more than 4.8 percent. The combined effect of both provisions remains a net increase in SFA competitive food revenue under all of these scenarios.[18]

It is also worth noting that USDA estimates that just over 98 percent of SFA competitive food revenue is generated by sales of à la carte foods and ''many foods are only offered à la carte when available as part of a reimbursable meal'' (SNDA–III, p. 119).[19] Under regulations that took effect July 1, 2012, school meals are currently required to meet new nutrition standards. Because the school meal standards are similar to those proposed for competitive foods, many of the foods served à la carte will meet the standards in the final competitive food rule before it takes effect. For other entrées and side dishes served as part of a reimbursable meal, the proposed rule would provide a limited exemption from competitive food requirements. In addition, the new school meal nutrition standards will provide an opportunity for schools and for industry to adjust to the new requirements before the competitive food standards take effect. In addition, at least 39 States currently have competitive food policies, the majority of which exceed existing Federal standards. In these States, industry may already have made a number adjustments to the products offered for sale.

Unlike SFAs other school groups cannot make up lost revenues through school meal sales. The proposed rule mitigates the impact of the proposed rule on such groups by providing an exception for occasional fundraisers that do not meet the proposed competitive food standards. Alternatively, these groups may explore fundraising options that include foods that do meet the proposed standards or find other modes of fundraising that do not include competitive foods.

Industry Groups

Manufacturers, wholesalers, foodservice management companies, and distributors, including vending machine operators, are not directly regulated under the proposed rule but may be affected indirectly in the sense that schools will need to purchase a different mix of foods to satisfy the requirements of the rule. However, many States have already adopted their own competitive food standards, and the food industry is already responding by producing a variety of products that meet current State as well as the proposed Federal standards. Consider, for example, that Wescott et al. (2012) found that between 2004 and 2009, the beverage industry reduced calories shipped to schools by 90 percent, with a total volume reduction in full-calorie soft drinks of over 95 percent.

Consistent with SBA guidance, which notes that ''[t]he courts have held that the RFA requires an agency to perform a regulatory flexibility analysis of small entity impacts only when a rule directly regulates them'' (SBA, p. 20),[20] we do not attempt to quantify the economic effect of the proposed rule on these industry groups. However, we briefly mention two industry groups that may be more directly affected by the rule than others.

(1) Vending.

Vending machine operators served an estimated 19,000 primary and secondary schools in the U.S. in 2008.[21] For 2008, the vending industry estimated that primary and secondary schools accounted for just two percent of total vending machine dollar sales. Both industry and U.S. Census data indicate that most vending machine operations are small businesses. The majority of vending machine operators that operated for the entire year in 2007 (76 percent) employed fewer than 10 individuals according to the U.S. Economic Census.[22] The same source also finds that 37 percent of vending machine operators that operated for all of 2007 generated less than $250,000 in receipts, although those operators accounted for less than 3 percent of total revenue from this industry group.[23] Because of the relatively large number of small vending machine operators, some small vendors may be challenged by the changes contained in the proposed rule. Whether small or large, many vending machine operators will need to modify their product lines to meet the requirements of the rule.

(2) Food Service Management Companies.

FSMCs are potentially indirectly affected by the proposed rule. FSMCs that provide à la carte foods to schools under contract to SFAs will need to provide foods that conform to the changes in the proposed rule. As with the SFAs, we anticipate that many of those costs will have already been incurred through changes in the school meal requirements.

Administrative Costs

The proposed rule requires that State agencies ensure that all schools, SFAs, and other food groups comply with its competitive food standards. State agencies must also retain documentation demonstrating compliance. Schools, SFAs, and other food groups are responsible for maintaining records documenting compliance with competitive food standards. It is anticipated that the administrative cost to 57 State agencies, 101,000 schools, and 21,000 SFAs will total $124 million over five years (or about $245 per school per year on average).

Distributional Impacts

A key characteristic associated with a school's dependence on competitive food revenue is grade level. High schools are more likely to offer competitive foods than are elementary schools. This is true of à la carte foods, foods sold through vending machines, and foods sold in school stores or snack bars.[24] Competitive food revenue is also associated with a school's mix of low and high income students. According to SNDA–III, schools serving at least one-third of their meals at full price to higher income students obtain more than seven times as much revenue from competitive food sales as schools serving a larger percentage of free and reduced-price (and hence lower-income) students.[25] Other factors that may be associated with student access to competitive food sources and school revenue from competitive foods include whether students have the option of leaving campus during the school day, and whether schools grant students the right to leave the cafeteria during meal times. Generally, student

[17] **Federal Register**, Vol. 76, No. 117, pp. 35301–35318.

[18] The same is not true of competitive food revenue of non-SFA school groups. Competitive food revenue that does not accrue to the foodservice account is not subject to regulation under Section 206.

[19] SNDA III: *www.fns.usda.gov/Ora/menu/Published/CNP/FILES/SNDAIII–Vol1.pdf.*

[20] SBA, ''A Guide for Government Agencies''.

[21] VendingTimes.com, Census of the Industry, 2009 Edition. Automatic Merchandiser magazine, June/July 2011.

[22] Data for NAICS code 454210, ''vending machine operators.'' U.S. Census Bureau, *http://www.census.gov/econ/industry/ec07/a454210.htm* (accessed 11/13/2011).

[23] Ibid. Note that these statistics are for all vending machine operators in NAICS code 4545210, not just those that serve the school market. We do not know whether the concentration of small vending machine operators that serve the school market differs from the concentration of small operators in the industry as a whole.

[24] U.S. Department of Agriculture, Food and Nutrition Service, 2007, School Nutrition Dietary Assessment Study-III, Vol. I by Mathematica Policy Research, Inc., (SNDA–III), pp. 73–77, 86–89.

[25] Unpublished ERS analysis of SNDA–III data.

mobility privileges increase with grade level.[26] These factors are not necessarily associated with school or SFA size.

The most important source of competitive food revenue is à la carte sales. Sales from vending machines are less common, accounting for only about five percent of all competitive food sales. In general, small schools are less likely than larger schools to have vending machines accessible to students: just 36 percent of schools with fewer than 500 students had vending machines. That increases to 48 percent of schools with 500 to 1,000 students and 78 percent of schools with more than 1,000 students.[27]

Federal Rules That May Duplicate, Overlap or Conflict with the Proposed Rule: FNS is unaware of any such Federal rules or laws.

Significant Alternatives: HHFKA requires USDA to establish standards that are consistent with the most recent Dietary Guidelines for Americans (DGA) using ''authoritative scientific recommendations'' (HHFKA section 208). The proposed rule standards reflect nutrition guidelines set forth in the 2010 DGA, by the National Academies' Institute of Medicine in Nutrition Standards for Foods in Schools (2007), standards already adopted by States and localities, and standards identified by other organizations.

The proposed rule reflects a considered balance among these guidelines. It is possible to derive an alternative, however, that would require fewer changes to allowed competitive foods. While different standards might reduce the cost of the rule for some regulated parties, there is little evidence that the economic costs of the rule fall disproportionately on the smallest SFAs, schools, or other school groups within these schools. A rule less closely aligned with DGA and other scientific recommendations would not provide particular relief to these small entities, but may result in fewer improvements to the school nutrition environment and children's health.

USDA also considered a separate implementation schedule for small entities.[28] This may offer smaller schools and businesses more time to adjust to the new requirements. But because the majority of competitive food revenues come from à la carte sales, and because à la carte foods will be subject to the new school meal pattern requirements, many à la carte foods will already meet healthier food standards when the proposed competitive food rule becomes effective. While vending machines are not subject to the meal pattern standards, they are more commonly found in large schools: over three quarters of schools with more than 1,000 students have vending machines as compared to a third of schools with fewer than 500 students.[29] FNS determined, therefore, that the potential benefit of deferring implementation for smaller schools would not outweigh the potentially adverse impact of deferring important improvements to the school nutrition environment for all children.

[26] Ibid., p. 78.

[27] Ibid., p. 88.

[28] A more permissive compliance schedule for small entities is one of the alternative cited in SBA, ''A Guide for Government Agencies,'' p. 35.

[29] SNDA–III., p. 88.

Regulatory Impact Analysis

Agency: Food and Nutrition Service, USDA.

Title: Nutrition Standards for All Foods Sold In School.

Nature of Action: Proposed Rule.

Need for Action: Section 208 of the Healthy, Hunger-Free Kids Act of 2010 requires the U.S. Department of Agriculture (USDA) to establish science-based nutrition standards for all foods sold in schools during the school day. The standards proposed in this rule are intended to help ensure that *all* foods sold at school—whether provided as part of a school meal or sold in competition with such meals—are aligned with the latest and best dietary recommendations. They will work in concert with recent improvements in school meals to support and promote diets that contribute to students' long-term health and well-being. And they will support efforts of parents to promote healthy choices for children, at home and at school.

Affected Parties: All parties involved in the operation and administration of programs authorized under the National School Lunch Act or the Child Nutrition Act that operate on the school campus during the school day. These include State education agencies, local school food authorities, local educational agencies, schools, students, and the food production, distribution, and service industry.

Abbreviations:

DGA Dietary Guidelines for Americans
FDA Food and Drug Administration
FMNV Foods of Minimal Nutritional Value
FY Fiscal Year
HHFKA Healthy, Hunger-Free Kids Act
IOM Institute of Medicine
NSLP National School Lunch Program
SBP School Breakfast Program
SFA School Food Authority
SLBCS–II School Lunch and Breakfast Cost Study II
SNDA–III School Nutrition Dietary Assessment III
SY School Year
USDA United States Department of Agriculture

Contents

I. Introduction

A. Overview

There has been increasing public interest in the rising prevalence of overweight and obesity in the United States, particularly among children. The school nutrition environment is a significant influence on children's health and well-being. Recent studies have shown that children typically consume between 26 and 35 percent of their total daily calories at school, and as much as 50 percent for children who participate in both school lunch and breakfast programs (Fox 2010; Guthrie, et al., 2009).

In response to these concerns, the Healthy Hunger-Free Kids Act (HHFKA) of 2010 required USDA to establish science-based nutrition standards for *all* foods sold in schools during the school day. The standards proposed here are intended to help ensure that *all* foods sold at school—whether provided as part of a school meal or sold in competition with such meals—are aligned with the latest and best dietary recommendations.

The proposed competitive food standards will work in concert with recent improvements in school meals to support and promote diets that contribute to students' long-term health and well-being. Congress highlighted the relationship between school meal improvements and standards for other school foods, noting that the prevalence of ''unhealthy [competitive] foods in our schools not only undermines children's health but also undermines annual taxpayer investments of over $15.5 billion in the National School Lunch and School Breakfast Programs'' (Senate Report 111–178, p. 8).

The benefits sought through this rulemaking focus on improving the food choices that children make during the school day. A growing body of evidence tells us that giving school children healthful food options will help improve these choices. A recent, comprehensive, and groundbreaking assessment of the evidence by the Pew

Health Group and Robert Wood Johnson Foundation concluded that:

• A national competitive foods policy would increase student exposure to healthier foods and decrease exposure to less healthy foods, and

• Increased access to a mix of healthier food options is likely to change the mix of foods that students purchase and consume at school, for the better.

Researchers for Healthy Eating Research and Bridging the Gap, Robert Wood Johnson Foundation-sponsored research programs examining environmental influences on youth diets and obesity, have concluded that strong policies that prohibit or restrict the sale of unhealthy competitive foods and drinks in schools improve children's diets and reduce their risk for obesity.

Because setting national standards will change the range of food products sold in schools, they may affect the revenues schools earn from these foods, as well as participation in school meals. The evidence on the overall impact of competitive food standards on school revenues is mixed. However, a number of schools implementing such standards have reported little change, and some increases, in net revenues.

B. Background

Children generally have two options for school food purchases: (1) Foods provided under the National School Lunch Program (NSLP), the School Breakfast Program (SBP), or other child nutrition programs authorized under the National School Lunch Act or the Child Nutrition Act, and (2) competitive foods purchased à la carte in school cafeterias or from vending machines at school. NSLP is available to over 50 million children each school day; an average of 31.8 million children per day ate a reimbursable lunch in fiscal year (FY) 2011. Additional children are served by the Child and Adult Care Food and the Summer Food Service Programs that operate from NSLP and SBP participating schools. While meals served through these programs are required to meet nutritional standards based on the most recent *Dietary Guidelines for Americans* (DGA), competitive foods are subject to far fewer Federal dietary standards. Existing regulations address only the place and timing of sales of foods of minimal nutritional value (FMNV).[30]

The sale of food in competition with Federal reimbursable program meals and snacks is widespread. In school year (SY) 2004–2005, 82 percent of all schools—and 92 percent of middle and high schools—offered à la carte foods at lunch. Vending machines were available in 52 percent of all schools, and 26 percent of elementary schools, 87 percent of middle schools, and 98 percent of high schools (Gordon, et al., 2007; Volume 1, pp. 102–114).[31] Revenues from competitive foods, however, are far smaller than revenues from USDA-funded school meals. In SY 2005–2006, approximately 84 percent of school food authority (SFA) revenue was derived from reimbursable school meals, from a combination of USDA subsidies, State and local funds, and student meal payments. The remaining 16 percent was derived from non-reimbursable food sales (USDA 2008, p. xii). Half of secondary school students consume at least one snack food per day at school, an average of 273 to 336 calories per day. This amount is significant considering that an excess of 110 to 165 calories per day may be responsible for rising rates of childhood obesity (Fox *et al* 2009, Wang *et al* 2006, cited in Pew Health Group, 2012).

Many observers, including parents and military leaders, have expressed concerns about the competitive foods available to children at school (Gordon, et al., 2007; Christeson, Taggart, and Messner-Zidell, 2010; Christeson, et al., 2012). In response, a number of States have implemented competitive food standards. In 2004, GAO reported that 21 States had created standards that went beyond existing Federal standards. In 2010, the School Nutrition Association reported that the number of States with competitive food policies had increased to 36.[32] [33] [34] More recently, the Centers for Disease Control and Prevention (CDC) reported that 39 States had established competitive food policies as of October 2010; in two of those States, legislation had recently passed to require competitive food standards, but neither State had yet defined specific standards.[35] A 2012 study conducted for FNS found that at least half of States had competitive food standards for foods sold in vending machines, à la carte, school stores, and snack bars, and almost half had nutrition standards for foods sold in bake sales (Westat, 2012, p., 5–25).

The Pew Health Group and Robert Wood Johnson Foundation recently reviewed data on the types of snack foods and beverages sold in secondary schools via vending machines, school stores, and snack bars.[36] The data were extracted from a biennial assessment from the CDC that uses surveys of principals and health education teachers to measure policies and practices across the nation. Key findings show:

• The availability of snack foods in secondary schools varies tremendously from state to state. This variation is likely the result of a disparate patchwork of policies at the state and local levels. Fewer than 5 percent of school districts have food and beverage policies that meet or exceed the 2010 Dietary Guidelines for Americans.

• ''Under this patchwork of policies, the majority of our nation's children live in states where less healthy snack food choices are readily available.''

Overall, the availability of healthy snacks such as fruits and vegetables is limited. The vast majority of secondary schools in 49 states *do not* sell fruits and vegetables in snack food venues (Pew Health Group, 2012).

C. Baseline Competitive Food Revenue

As shown in Table 1, we estimate that overall revenue in SFAs will be about $34 billion to $36 billion each fiscal year between 2015 and 2018. Overall revenue includes the value of Federal reimbursements for NSLP and SBP meals,[37] student payments, and State and local contributions. This estimate is derived from the relationship between Federal reimbursements and total SFA revenue estimated in the School Lunch and Breakfast Cost Study (SLBCS–II) (USDA 2008).

USDA's most recent budget projections forecasted a total of $16.0 billion in Federal meal reimbursements in FY 2014, exclusive of the effects of sections 205 and 206 of HHFKA on Federal reimbursements and competitive food revenue. We use findings from the SLBCS–II about the relationship between Federal meal reimbursements and overall SFA revenue to derive an estimate of $31.6 billion in SFA revenue in FY 2014, and then adjust this upward for HHFKA impacts [38] to a total of $33.5 billion in SFA revenue in that year.

Our estimate of competitive food revenues under current policies and practices also uses

[30] FMNV include carbonated beverages, water ices, chewing gum, hard candy, jellies and gums, marshmallow candies, fondant, licorice, spun candy, and candy-coated popcorn. The current policy restricts the sales of FMNV during meal service in food service areas. See 7 CRF 210.11.

[31] SNDA–III found the top five most commonly offered à la carte lunch items were milk, juice and water, snacks, baked goods, and mixed dishes (for example, salads, pizza, etc.). For vending machines, the top five most commonly offered items included juice and water, other beverages (for example, carbonated and energy drinks, coffee and tea, etc.) snacks, baked goods, and bread or grain products.

[32] GAO–04–673. April 2004. The GAO identified 23 States, but 2 of the 23 had only created committees to assess competitive food issues. The report considered both timing of competitive foods sales and the types of products offered. In terms of timing, of the 21 States with competitive food policies, 14 limited access to competitive foods at times associated with meal periods, 5 limited competitive food sales during the entire school day, and 2 States varied the standards by the type of school. In terms of the types of foods, 6 of the 21 States limited access to all competitive foods, 8 limited access only to FMNV, and 7 States limited selected competitive foods. Seventeen of the States limited access at all grade levels, while the remaining 4 States had policies that applied only to selected schools. GAO also found that within States, individual schools and districts had policies that were stricter than the State standards.

[33] A recent study by Taber, et al. (2011), takes a broad look at State competitive food standards, utilizing CDC data to estimate effects of State policy changes between 2000 and 2006.

[34] Similar to the GAO report, a report from the School Nutrition Association (SNA) indicates 23 States had competitive food policies on or before 2004. There is at least one difference among the States identified by GAO and those identified by SNA, but it is not clear how many other discrepancies may exist.

[35] CDC included State laws, regulations, and policies enacted or passed since October 2010. We use the term policy to generically refer to all three.

[36] ''Out of Balance: A Look at Snack Foods in Secondary Schools across the States,'' The Pew Health Group and the Robert Wood Johnson Foundation (2012). The report examines data contained in N. D. Brener et al., ''School Health Profiles 2010: Characteristics of Health Programs Among Secondary Schools in Selected U.S. 21 Sites,'' U.S. Department of Human Services, Centers for Disease Control and Prevention (2011).

[37] an estimate prepared for the FY 2013 President's Budget.

[38] The estimated increase in SFA revenues in 2014 from these provisions is $581 million for reimbursable meals, and $1.3 billion for competitive food revenue, for a total increase of about $1.9 billion. See 76 **Federal Register** 35301–35318, especially p. 35305.

SLBCS–II,[39] which showed that SFA competitive food revenue accounted for 15.8 percent of overall SFA revenue prior to HHFKA. For FY 2014, we begin with the estimated $31.6 billion in SFA revenue that excludes the effects of HHFKA on Federal meal reimbursements and student payments for program meals and competitive foods. For FY 2014, that implies baseline SFA competitive food revenues of $5.0 billion.[40] We add an estimated $1.3 billion increase in competitive food revenue from HHFKA Section 206 to get an adjusted $6.3 billion in SFA competitive food revenue.

To estimate the proportions of these revenues generated by à la carte sales and vending machines, we use SNDA–III data to show that about 98.3 percent of SFA competitive food revenue was generated by sales of à la carte foods; virtually all of the rest, 1.7 percent, was generated by vending machine sales.

Data from SNDA–III indicate that 95 percent of competitive food revenue accrues to SFA accounts; just five percent of competitive food revenue accrues to non-SFA student, parent and other school group accounts.[41] Our estimate of competitive food revenue generated by these groups in the last three months of FY 2014 is $40 million.[42] If none of the competitive food revenue raised by non-SFA school groups comes from à la carte, then à la carte sales accounted for roughly 93 percent (= 0.98 × 0.95) of total SFA and non-SFA competitive food revenue in SY 2004–2005.

We inflate these full-year figures for 2015 through 2018 based on the assumptions in the President's Budget. Because this analysis assumes that the rule will take effect in July 2014, the start of SY 2014–2015, we reduce the FY 2014 figures in Table 1 to include only the last three months of the fiscal year—about 15 percent of the full-year figures.[43]

TABLE 1—BASELINE COMPETITIVE FOOD AND OVERALL SFA REVENUE

	Fiscal year (millions)					
	2014	2015	2016	2017	2018	Total
Baseline SFA revenue (all sources)	$5,062	$34,045	$34,694	$35,350	$36,451	$145,601
Baseline competitive food revenue	993	6,758	6,921	7,102	7,296	29,070
SFA revenue	954	6,492	6,651	6,828	7,013	27,938
à la carte	937	6,382	6,538	6,712	6,894	27,463
vending and other sources	16	110	113	116	119	475
Other school group revenue	40	266	270	274	283	1,132
à la carte	0	0	0	0	0	0
vending and other sources	40	266	270	274	283	1,132

Other school groups generate their competitive food revenue from periodic fundraisers, vending machines, snack bars, and school stores. These groups include student clubs, parent teacher organizations, or parent organizations supporting sports, music, and other enrichment activities. Much of the non-SFA competitive food revenue is controlled by school principals for special school events, sports, or general fundraising.

Given the implementation of Section 206 and significant State and local school food initiatives adopted since SY 2004–2005, our baseline estimate of competitive food revenue generated by other school groups is highly uncertain. We encourage reviewers of this proposed rule to offer additional information that might improve these estimates through the regulatory comment process.

D. Previous Recommendations and Existing Standards

Although HHFKA established Federal authority for comprehensive nutrition standards for all foods in school, efforts to define and implement such standards have been underway for a number of years. Our analysis briefly describes these activities to provide additional context for the proposed rule.

1. Institute of Medicine Recommendations

In 2005, Congress directed CDC to commission the Institute of Medicine (IOM) to develop a set of nutrition standards for competitive school foods (House Report 108–792). Nutrition Standards for Foods in Schools: Leading the Way toward Healthier Youth set forth its recommendations for nutrient and other standards. The committee first identified a set of guiding principles, recognizing that:

a. The present and future health and well-being of school-age children are profoundly affected by dietary intake and the maintenance of a healthy weight.

b. Schools contribute to current and lifelong health and dietary patterns and are uniquely positioned to model and reinforce healthful eating behaviors in partnership with parents, teachers, and the broader community.

c. Because * * * foods and beverages available on the school campus represent significant caloric intake, they should be designed to meet nutrition standards.

d. Foods and beverages have health effects beyond those related to vitamins, minerals, and other known individual components.

e. Implementation of nutrition standards for foods and beverages offered in schools will likely require clear policies; technical and financial support; a monitoring, enforcement, and evaluation program; and new food and beverage products (IOM, 2007a, p. 3).

The committee then identified its intentions:

[39] For purposes of this analysis we assume that the revenue generated from competitive food sales has increased at the same rate as the growth in SFA revenue from reimbursable paid lunches. For years after FY 2010, we assume that baseline competitive food revenue will increase at the same rate as the projected increase in SFA revenue from reimbursable paid lunches contained in the FY 2013 President's Budget.

[40] $31.6 billion × 15.8% = $5.0 billion.

[41] ERS analysis of unpublished data from the third School Nutrition Dietary Assessment Study (SNDA–III). Note that SNDA–III may underestimate other school group revenues to the extent that these groups share in revenue from school stores that sell food or engage in separate fundraising events. SNDA–III reports that 44 percent of schools allow student group fundraisers, but 75 percent of those schools tend to hold them less than once per week. Just 14 percent of schools operated snack bars or school stores that might generate revenue for non-SFA school groups. For this reason, we believe that our estimates capture the larger share of revenue raised by these groups. According to SNDA–III's principals' surveys, 44 percent of schools sold competitive foods in vending machines and through periodic fundraisers in SY 2004–2005. Just 11 percent of schools sold competitive foods in school stores, and just 3 percent sold competitive foods in school snack bars. See Gordon, et al., 2007, vol. 1, pp. 77–79.

[42] Because other school groups do not generate revenue from à la carte sales, we start with the SFA competitive food revenue excluding our estimate of the SFA competitive food revenue increase from HHFKA, which is almost entirely from à la carte sales. Our FY 2014 competitive food baseline for other school groups is therefore: [($31.6 billion × 15.8 percent) ÷ 0.95] × .05 = $263 million. The part year effect for the last three months of FY 2014 reduces that to $40 million.

[43] The FY 2014 figures in Table 1 are just 15.1 percent of our full year FY 2014 estimates. 15.1 percent is the ratio of paid reimbursable lunches served from July through September 2011 to the number of paid reimbursable lunches served from October 2010 through September 2011. We use paid reimbursable lunches, rather than total lunches or total Federal reimbursements, as the best proxy (among available administrative data) for the share of competitive foods purchased in the first three months of the fiscal year. An unpublished ERS analysis of SNDA–III data found that schools with the greatest share of children eligible for paid meals generate far more competitive food revenue than schools with higher percentages of free or reduced-price eligible children. For SFA revenue, the figure in Table 1 is equal to $33.6 billion × 15.1 percent, or $5.1 billion.

• The federally reimbursable school nutrition programs will be the primary source of foods and beverages offered at school.
• All foods and beverages offered on the school campus will contribute to an overall healthful eating environment.
• Nutrition standards will be established for foods and beverages offered outside the federally reimbursable school nutrition programs.
• The recommended nutrition standards will be based on the Dietary Guidelines for Americans, with consideration given to other relevant science-based resources.
• The nutrition standards will apply to foods and beverages offered to all school-age children (generally ages 4 through 18 years) with consideration given to the developmental differences between children in elementary, middle, and high schools (IOM, 2007a, p. 3).

Finally, the Committee recommended a two-tier system: Tier 1 consisting of foods and beverages to be encouraged and Tier 2 consisting of snack foods that do not meet Tier 1 criteria but still meet the recommendations for fats, sugars, and sodium set forth in the DGA.

Under the IOM recommendation, à la carte entrées would be required to be on the NSLP menu and meet Tier 1 criteria with two exceptions: the amount of allowed sodium would increase from 200 milligrams (mg) to no more than 480 mg, and the 200 calorie limit imposed on Tier 1 foods would not apply; à la carte entrées would have to meet the calorie content of comparable NSLP entrée items.

2. Voluntary Standards

USDA's *HealthierUS School Challenge* (HUSSC), and the Alliance for a Healthier Generation's *Healthy Schools Program* offer two models of voluntary standards adopted by many schools across the country.

HUSSC began in 2004 as a way to promote healthier school environments through nutrition and physical activity, with four award levels: bronze, silver, gold, and gold of distinction. HUSSC includes standards for competitive foods that are similar to the standards in the proposed rule. At all award levels, competitive foods and beverages must meet the following standards:
• No more than 35% of calories from total fat (excluding nuts, seeds, nut butters and reduced-fat cheese),
• Less than 0.5 grams (g) trans fats per serving,[44]
• No more than 10% saturated fat (reduced-fat cheese is exempt),
• Total sugar must be at or below 35% by weight (includes naturally occurring and added sugars. Fruits, vegetables, and milk are exempt),
• Portion sizes may not exceed the serving size of the food served in school meals and other competitive foods may not exceed 200 calories as packaged.
• Only low-fat or fat-free milk and USDA approved alternative dairy beverages may be offered,
• Milk serving size is limited to 8-fluid ounces,
• Fruit and vegetable juices must be 100% full strength with no sweeteners or non-nutritive sweeteners, and
• Water that is non-flavored, non-sweetened, non-carbonated, non-caffeinated, without non-nutritive sweeteners is allowed.
• For bronze and silver awards, competitive food standards apply to foods sold in the meal service area during meal periods.
• For gold and gold of distinction awards, competitive food standards apply anywhere in the school and at any time during the school day.
• For bronze, silver, and gold awards, sodium cannot exceed 480 mg for snack foods or 600 mg for entrées.
• For gold of distinction awards, sodium cannot exceed 200 mg for snack foods or 480 mg for entrées.

As of January 2013, almost 5,000 schools in 49 States and the District of Columbia were certified HUSSC schools, and all of these schools, regardless of award level, have already moved at least part way to the proposed competitive food standards.[45]

Schools that are a part of the Alliance for a Healthier Generation's Healthy Schools Program voluntarily adopt competitive food standards that require:
• No more than 35 percent of calories from total fat,
• No more than 10 percent of calories from saturated fat,
• 0 g trans fat, and
• No more than 480 mg sodium.

The Alliance for a Healthier Generation also recommends schools serve whole grain products; fresh, canned, or frozen fruit (in fruit juice or light syrup); and non-fried vegetables. The more than 14,000 schools currently participating in the Alliance for a Healthier Generation Healthy Schools Program have also moved towards the standards in the proposed rule.[46]

3. Competitive Food Standards in Five Largest States

The five States with the largest numbers of students enrolled in NSLP-participating schools are California, Florida, Illinois, New York, and Texas. These States account for 37 percent of all students enrolled nationally in NSLP participating schools (18.7 million students). All five of these States have had school competitive food policies since 2004 or earlier. School districts in these States have already confronted some of the challenges of transitioning students toward improved competitive foods and have dealt with the consequences of any changes in overall revenues.

In *California,* elementary children may purchase only milk (2% or less), fruit or vegetable juices that are at least 50 percent juice with no added sweeteners, and water with no added sweeteners. Generally, foods must not have more than 35 percent of calories from fat, 10 percent of calories from saturated fat, and 0 calories from trans fat, and no more than 35 percent sugar by weight. Nuts, nut butters, seeds, eggs, cheese packaged for individual sale, fruit, vegetables that have not been deep fried, and legumes are also allowed for purchase. These standards apply regardless of the time of day.

Middle and high school children may purchase water, milk (2% or less), fruit and vegetable drinks that are at least 50 percent juice, and electrolyte replacement beverages with no more than 2.1 g of added sweetener per one fluid ounce. They may also purchase food items à la carte as long as the foods have no more than 400 calories per entrée and no more than four g of fat per 100 calories. Entrées from NSLP meals are also allowed. These standards are in place from 30 minutes before the school day through 30 minutes after the school day (CSPI, 2007).

Florida does not allow any competitive food sales on elementary school campuses during the day and does not allow competitive foods from vending, school stores, and other food sales in secondary schools until an hour after the last lunch period. Carbonated beverages are allowed if 100 percent fruit juices are also available where those beverages are sold (CSPI, 2007).

Illinois policy on competitive foods applies only to grades eight and below, for foods sold during the school day, with the exception of foods that are sold as part of a reimbursable meal or sold within the food service area. Allowable beverages include water, milk, fruit and vegetable drinks that are at least 50 percent fruit juice and yogurt or ice-based smoothie drinks with fewer than 400 calories that are made with fresh or frozen fruit or fruit drinks containing at least 50 percent fruit juice.

Foods that are allowed to be sold outside food service areas or within food service areas other than during meal service must have no more than 35 percent of calories from fat and 10 percent of calories from saturated fat, no more than 35 percent sugar by weight, and may not contain more than 200 calories per serving. Nuts, seeds, nut butters, eggs, cheese packaged for individual sale, fruits or non-fried vegetables, or lowfat yogurt products are also allowed (CSPI, 2007).

New York State broadly restricts the sales of FMNV and ''all other candy'' from the beginning of the school day through the end of the last scheduled meal period. New York's State Education Department, however, allows competitive food standards to be set at the district level (DiNapoli, 2009), and New York City, for example, has adopted standards that are much more rigorous than the State-level standards.

Competitive food sales standards within New York City schools apply to food sales from the beginning of the school day through 6 p.m. weekdays. Students can sell New York State Department of Education approved foods in schools any time during the day, as long as the sale occurs outside of the school cafeteria. PTAs can hold a monthly fundraiser during the day with non-approved food items as long as the sale occurs outside

[44] Current rules allow manufacturers to report a product has ''zero grams'' of trans fat as long as there are less than 0.5 g trans fat per serving. See 21 CFR Part 101.62.

[45] FNS HealthierUS School Challenge at *http://www.fns.usda.gov/tn/healthierus/index.html.* A nutrition standards chart is available at *http://www.fns.usda.gov/tn/healthierus/award_chart.pdf.*

[46] School participation numbers are from the Healthy School Program, Alliance for a Healthier Generation Web site. *http://www.healthiergeneration.org/schools.aspx.*

the cafeteria and complies with standards set in the Chancellor's Regulations. Allowed beverages include water or low-calorie drinks without artificial flavors or colors, at 10 calories per eight ounces for elementary and middle schools and 25 calories per eight ounces in high schools. Lowfat (1%) and fat free milk are also allowed.

Snack vending machines are not permitted in schools with students in pre-kindergarten through fifth grade. For students above grade five, competitive foods must have no more than 35 percent of calories from fat (nuts and nut butters are exempt), less than 10 percent of calories from saturated fat, and 0.5 g or less of trans fat; no more than 35 percent of calories from sugar (fruit products with no added sugar are exempt), less than 200 total calories, may not exceed 200 mg sodium, and grain-based products must contain at least two grams of fiber per serving (New York City, 2010).[47]

Texas State policy does not allow the sale of FMNV or any food or beverage that is not provided by school food service on elementary school campuses until after the end of the last scheduled class period (CSPI, 2007). Allowed beverages include milk (2% or less), water, and 100 percent vegetable or fruit juices. For middle schools, FMNV, candy, and carbonated beverages sales are not permitted until the last scheduled class. Twelve ounce containers of beverages, other than milk and FMNV, with no more than 30 g sugar per eight ounces are allowed. These beverages might include sports and fruit drinks and sweetened ice teas.

At the high school level, FMNV may be sold only after the last scheduled class. Sugared and carbonated beverages of no more than 12 ounces may be offered, but only 15 percent of vending machine slots or service points may be devoted to these beverages. In all grades, individual food items may not contain more than 23 g of fat per serving, with the exception that once per week one food with 28 g (1 ounce) of fat per serving is allowed.

Schools must eliminate deep-fat frying as a method of on-site preparation for foods served as part of reimbursable school meals, à la carte, snack lines, and competitive foods. Servings of potatoes may not exceed three ounces, may be offered no more than once per week, and students may only purchase one serving at a time. Baked potato products (wedges, slices, whole, new potatoes) that are produced from raw potatoes and have not been pre-fried, flash-fried or par-fried in any way may be served without restriction. Fruit and/or vegetables must be offered daily on all points of service (CSPI, 2007).

While none of these States have policies that match all of the standards in the proposed rule, California, Illinois, and New York City meet several: California meets or exceeds the proposed standards for calories; total, saturated, and trans fats; and sugar. Illinois meets proposed standards for calories, total and saturated fat, and sugar. New York City meets proposed standards for total, saturated, and trans fats, sodium, and sugar. On the other end of the spectrum, Texas only provides a standard for total fat (though it is more restrictive than the proposed rule), and Florida does not set specific nutrient standards.

Table 2 provides a summary description of a number of existing sets of nutrition standards that are in already in place. These include two voluntary programs: USDA's HealthierUS Schools Challenge and the Alliance for a Healthier Generation's Healthy Schools Program. We have also outlined the standards in effect in four of the five States with the largest numbers of students enrolled in NSLP-participating schools.[48]

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[48] Florida is not included in this summary table because it does not identify nutrient standards. Instead, it bans competitive food sales on elementary school campuses during the school day and does not allow competitive foods from vending, school stores, and other food sales in secondary schools until an hour after the last lunch period.

Table 2: Current Competitive Food Standards[49]

Nutrition Standards (per serving)	HealthierUS Schools (gold of distinction level)	Alliance for a Healthier Generation	California	Illinois*	New York City**	Texas
Calories	q 200 calories (snack) = NSLP serving size (entrée)	150, 180, and 200 (Snack only) (elementary, middle, and high school)	-- 400 calories per entrée (middle and high school)	-- --	q 200 calories (snack) --	-- --
Sodium	q 200 mg (snack) q 480 mg (entrée)	q 230 mg (snack) --	-- --	-- --	q 200 mg (snack) --	-- --
Sugar	q 35 % by weight	q 35 % by weight	q 35 % by weight	q 35 % by weight	q 35% of calories	
Total fat	q 35 %	q 35 %	q 35 %	q 35 %	q 35 %	q 23 g
Saturated fat	< 10%	< 10%	< 10%	< 10%	< 10%	--
Trans fat	< 5% (trans fat free)	0%	0%	0%	< 5% (trans fat free)	--
Milk	8 oz 1% or less	1% or less (must meet calorie	2% or less	--	1% or less	2% or less
Juice	6oz 100% juice	--	50% juice	50% juice	--	100% juice

*HUSSC has four levels – bronze, silver, gold, and gold of distinction. The nutrition standards for all levels are the same with the exception of sodium. For bronze through gold, the sodium standard is ≤ 480 mg for non-entrées and ≤ 600 mg for entrées.
** Illinois standards apply only to grades 8 and below.
***New York City standards apply to 5th grade and above. Competitive foods are not allowed for younger school children in New York City.

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II. Development of Federal Standards

Section 208 of the HHFKA, requires USDA to establish science-based nutrition standards for all foods and beverages sold on school campuses during the school day. These standards must be consistent with the most recent DGA and authoritative scientific recommendations (HHFKA, 2010, p. 98). The proposed rule addresses all competitive foods and beverages sold on campuses throughout the school day. It is guided by the same principles that underlie the 2007 IOM recommendations. At the same time, in developing the rule FNS reviewed existing currently implemented State and local school nutrition and voluntary standards to promote practicality and ease of implementation.

The proposed rule improves the competitive food options available to students by replacing less healthy items with appropriately sized entrées, side dishes, and snacks that emphasize foods from the food groups that are the basis of a healthy diet, consistent with the DGA. In this way, the rule is designed to help ensure the success of school meal standards introduced in July 2012. However, the rule does not prescribe a specific set of competitive foods, nor does it establish targets for particular food groups. Instead, the proposed rule puts students in a position to make their own healthy choices, and encourages the development of healthy habits for life.

The proposed rule establishes guidelines for all foods sold outside of school meal programs on the school campus at any time during the school day. The school day for purposes of this rule extends from midnight to 30 minutes past the end of the official school day. The school campus includes all areas under jurisdiction of the school that are accessible to students.

[48] Florida is not included in this summary table because it does not identify nutrient standards. Instead, it bans competitive food sales on elementary school campuses during the school day and does not allow competitive foods from vending, school stores, and other food sales in secondary schools until an hour after the last lunch period.

[49] Many of the standards provide exemptions for nuts, nut butters, seeds, and fruits, etc. Those exemptions are not shown in the table.

• Schools may allow the sale of food that does not meet proposed rule standards for school-sponsored fundraisers at a frequency to be determined with the help of public comments on the proposed rule. Exempted fundraiser foods may not be sold in competition with school meals.

• NSLP/SBP entrées and side dishes sold à la carte, with the exception of grain-based desserts which must always meet all nutrition standards, will be exempt from proposed rule standards subject to one of two alternatives. Alternative A1 would allow NSLP/SBP menu items that meet the proposed fat and sugar standards to be sold à la carte at any time. Alternative A2 would exempt NSLP/SBP entrées and side dishes from all standards if sold during menu cycles, with two alternate limitations (B1–B2)—that they can only be sold 1) on the day that they are served as part of a meal, or 2) within four operating days of the day they are served. USDA invites comments on these alternative standards.

Competitive foods must meet all the proposed nutrient standards, and must:

• Contain 50 percent or more whole grains or have whole grains as the first ingredient or be one of the non-grain main food groups as defined by the 2010 DGA: Fruit, vegetable, dairy product, protein foods (meat, beans, poultry, seafood, eggs, nuts, seeds, etc.); or

• Contain 10 percent of the daily value of a naturally occurring nutrient of public health concern from the DGA (e.g., calcium, potassium, vitamin D or dietary fiber), or

• Be a combination food that contains a half serving (¼ cup) of a fruit or vegetable.

If water is the food's first ingredient, the second ingredient must satisfy the standard above.

• Fresh, canned, and frozen fruits or vegetables with no added ingredients except water, or in the case of fruit, packed in 100 percent juice or extra light syrup, are exempt from the proposed rule's nutrient standards.

• Competitive foods must contain 35 percent or less of total calories from fat per portion as packaged. Exceptions from these fat standards are granted for reduced fat cheese, nuts, seeds, nut or seed butters, products consisting of only dried fruit with nuts and/or seeds with no added nutritive sweeteners or fat, seafood with no added fat.

• Competitive foods must contain no more than 10 percent of total calories from saturated fat, with the exception of reduced fat cheese.

• Competitive foods must have 0 g of trans fat.

• Sodium content in snacks is limited to 200 mg per portion as packaged for non-NSLP/SBP snack items. Non-NSLP/SBP entrée items must have no more than 480 mg of sodium per portion.

• Two alternative sugar standards are provided for comment. The first would limit total sugar to 35 percent of *calories.* The second would limit total sugar to 35 percent of *weight.* Under both alternatives, exceptions are provided for fresh, frozen, and canned fruits or vegetables with no added sweeteners except for fruits packed in 100 percent juice or extra light syrup, and dried whole fruits or vegetables, dried whole fruit or vegetable pieces, and dried dehydrated fruits or vegetables with no added nutritive sweeteners. Lowfat or nonfat yogurt with less than 30 g of sugar for eight ounces is also permitted.

• In general, competitive foods shall have no more than 200 calories per portion as packaged including accompaniments such as butter, cream cheese, salad dressing, etc. for snack items and side dishes sold à la carte. Entrée items sold à la carte shall contain no more than 350 calories.

• Accompaniments should be pre-portioned and must be included in the nutrient profile as a part of the item served and meet all the proposed standards.

• Elementary and middle school foods and beverages must be caffeine free with the exception of naturally occurring trace amounts.

• Allowable beverages for elementary students are limited to plain water, low fat milk, nonfat milk (including flavored), nutritionally equivalent milk alternatives (as permitted by the school meal requirements), and 100 percent fruit or vegetable juices. All beverages must be no more than eight ounces with the exception of water, which is unlimited.

• Allowable beverages for middle school students are limited to plain water, low fat milk, nonfat milk (including flavored), nutritionally equivalent milk alternatives (as permitted by the school meal requirements), and 100 percent fruit or vegetable juice. All beverages must be no more than 12 ounces, with the exception of water (which is unlimited).

• Allowable beverages for high school students are limited to plain water, lowfat milk, nonfat milk (including flavored), nutritionally equivalent milk alternatives (as permitted by the school meal requirements), and 100 percent fruit or vegetable juice. Milk and milk equivalent alternatives and fruit or vegetable juice must be no more than 12 ounces. Calorie-free, flavored and/or unflavored carbonated water and other calorie free beverages that comply with the FDA standard of less than five calories per serving must be no more than 20 ounces.

• Two alternative standards for low calorie beverages for high school students are provided for comment. The first alternative would allow beverages of up to 40 calories per 8 fl oz serving (or 60 calories per 12 fl oz). The second would allow up to 50 calories per 8 fl oz (or 75 calories per 12 fl oz). Both alternatives limit serving sizes to 12 fluid ounces or less. Beverages containing caffeine are permitted at times other than at meal service. There is no ounce restriction on water.

III. Cost-Benefit Analysis

The proposed rule requires schools to improve the nutritional quality of foods offered for sale to students outside of the Federal school lunch and school breakfast programs. Changing the mix of competitive foods offered by schools will likely change student expenditures on those foods, with potential implications for school food service revenues. It may also change the extent to which students purchase reimbursable school meals, resulting in changes in amounts transferred from USDA to SFAs and from students to SFAs for reduced price and paid meals.

This analysis examines a range of possible responses of students and schools, and resulting changes in school revenue, based on the experience of States, school districts, and schools with similar standards. While evidence on the overall impact of competitive food standards on school revenues is mixed, a number of schools implementing such standards have reported little change, and some have seen increases, in net revenues. Our analysis illustrates a range of possible revenue impacts, all of which are relatively small (+0.4 percent to −0.7 percent). By way of comparison, USDA has previously estimated that the combined effect of the other school food service revenue provisions included in HHFKA are expected to increase overall school food revenue by roughly six percent.[50] The combined effect of that rule and this proposal is a net increase in SFA revenue.

The key benefit sought through this proposed rule is to improve the food choices that children make during the school day. By helping to ensure that *all* foods sold at school—those provided as part of a school meal or sold in competition with such meals—are aligned with the latest and best dietary recommendations, the rule should also improve the mix of foods that students purchase and consume at school.

In turn, though the complexity of factors that influence overall food consumption and obesity prevent us from defining a level of dietary change or disease or cost reduction that is attributable to the rule, there is evidence that standards like those proposed in the rule will positively influence—and perhaps directly improve—eating patterns that contribute to students' long-term health and well-being, and reduce their risk for obesity.

A. Existing Research on Revenue Effects

If the proposed standards are finalized and implemented, students who currently purchase competitive foods will adjust their behaviors in a number of ways in response. Some students will accept the new competitive food offerings. Some will not and will turn instead to the Federal reimbursable meals programs. Other students will replace school food purchases with food from home. And, where the option exists, students may spend their competitive food dollars off campus. Student responses, in turn, will depend on the ability of schools, food manufacturers, and the foodservice industry to offer appealing choices.

It is instructive to begin with a review of studies and evaluations of existing State and local standards. While none of the existing standards are fully aligned with the provisions of the proposed rule, they offer the best available insight into the likely consequences of the proposed rule on school revenues and costs.

A number of studies have looked at the effects of implementation of nutrition standards on school food service revenues in a handful of States:

[50] *http://www.fns.usda.gov/cnd/Governance/regulations/2011-06-17.pdf.*

• A series of studies examined California's Linking Education, Activity and Food (LEAF) pilot program (Woodward-Lopez et al. 2005a; Vargas et al 2005). Among 16 high schools that received LEAF grants to implement competitive food standards adopted by California, 13 reported increases in total food service revenues, usually through increased reimbursable meal sales that offset a concurrent decrease in à la carte sales. Net income increased in three of the five sites that provided data on expenditures, and fell at the other two sites. It is not clear how much of the observed effects are solely due to the changes in competitive food standards because the pilot schools received grants ranging from about $200,000 to $740,000 for a 21 month implementation period (Center for Weight and Health, 2005).

• A related assessment of the impact of California's legislated nutrition standards reports that 10 of 11 schools that reported financial data experienced increases of more than five percent in total food and beverage revenue after implementation (Woodward-Lopez et al. 2010). Among the five schools that provide data for non-food service sales of competitive foods and beverages, four experienced a decrease in revenue of more than five percent and one experience a modest increase.

• An estimated 80 percent of surveyed principals in West Virginia reported little or no change in revenues after implementation of a state policy requiring schools to offer healthier beverages and restrict ''junk foods'' and soda (West Virginia University, 2009).

• Pilot projects in Connecticut and Arizona report, in some cases, increased food sales, increased meal participation, and no significant change or loss in food service revenue (Long, Henderson, and Schwartz, 2010; Arizona Healthy School Model Policy Implementation Pilot Study, 2005).

• Green Bay, Wisconsin officials reported that ''[w]hen low-nutrient foods were removed from à la carte lines and replaced with healthful alternatives, daily à la carte revenue decreased by an average of 18 percent. However, the decreased emphasis on à la carte sales prompted a 15 percent increase in school meal participation[!]. The revenue generated by the additional school meals more than doubled the lost à la carte revenue. Therefore, bottom-line dollars for school foodservice have increased overall'' (USDA, et al., 2005, p. 98).

• South Carolina's Richland One District ''reported losing approximately $300,000 in annual à la carte revenue after implementing [competitive food] changes, [but] school lunch participation and subsequent federal reimbursements increased by approximately $400,000 in the same year'' (GAO 2005, p. 43).

• Wharton, Long, and Schwartz (2008) reviewed ''the few available'' revenue-related articles and studies focused on healthier competitive food standards and determined that the ''* * * data suggest that most schools do not experience any overall losses in revenue'' after implementing healthier standards (p. 249).

• Most studies have assessed the impact of nutrition policies in the immediate post-implementation period. A recent effort examined longer-term impacts. Comparing revenue data over three years from 42 middle schools in five States, half of which adopted healthier competitive food standards, Treviño et al. (2012) found no difference and concluded that providing healthier food options is affordable and does not compromise school food service finances.

The Pew Health Group addressed the issue of revenue changes due to healthier competitive foods in its recent Health Impact Assessment (HIA). After analyzing the relationship between State policies and school-related finances, Pew researchers concluded that:

[W]hen schools and districts adopted strong nutrition standards for snack and a la carte foods and beverages, they generally did not experience a decrease in revenue overall. In most instances, school food service revenues increased due to higher participation in school meal programs. However, in some cases, school districts experienced initial declines in revenue when strengthening nutrition standards. The HIA concluded that, over time, the negative impact on revenue could be minimized—and in some cases reversed—by implementing a range of strategies (Pew HIA, p. 4).

Similarly, after reviewing the evidence, the National Center for Chronic Disease Prevention and Health Promotion at CDC concluded that ''[w]hile some schools report an initial decrease in revenue after implementing nutrition standards, a growing body of evidence suggest that schools can have strong nutrition standards and maintain financial stability'' (CDC, *Implementing Strong Nutrition Standards for Schools: Financial Implications,* p. 2).

While the existing research suggests that any impact of competitive food standards is likely to be relatively modest, there is substantial variation in the experience and results to date. The information available indicates that many schools have successfully introduced competitive food reforms with little or no loss of revenue. In some of those schools, losses from reduced sales of competitive foods were fully offset by increases in reimbursable meal revenue. In other schools, students responded favorably to the healthier options and competitive food revenue increased or remained at previous levels. But not all schools that adopted or piloted competitive food standards fared as well. These experiences vary so widely that they do not support a meaningful quantitative national estimate of the proposal's net impact on program costs and revenues.

B. Estimating School Revenue Changes

To assess the impacts of the proposed rule on school revenue, we reviewed the evidence summarized above and identified three scenarios for student behavior and estimated the revenue changes that could result:

• Scenario 1: Relatively high student acceptance of new competitive foods, thereby allowing schools to maintain existing competitive food sales.

• Scenario 2: Lower competitive food sales with fully offsetting increases in school meal participation.

• Scenario 3: Lower competitive food sales with partially offsetting increases in school meal participation.

We assume that the percentage change in NSLP participation (ΔL) following implementation of competitive food standards will be directly related to the percent change in competitive food purchases (ΔCF), since a portion of competitive food purchases are for lunch consumption. We assume that the change in competitive food revenue occurs largely from students whose response to new standards takes the form of increased or decreased demand, and that all other students maintain previous levels of purchasing.[51] Students who do not buy the new options are assumed to behave as if competitive foods were not available, and we model their behavior using the effect of competitive foods availability on NSLP participation as measured by Gordon, et al. (2007). ΔL is then the product of ΔCF and the competitive foods availability effect (CFAE) divided by the baseline NSLP participation rate (PR):[52]

$$\Delta L = \Delta CF \times CFAE/PR$$

The value for CFAE is assumed to be −4.6 percentage points, based on the finding by Gordon, et al. (SNDA III, vol. 2, p. 117) that the NSLP participation rate was 4.6 percentage points higher in schools that did not offer competitive foods during mealtimes compared to those that did. The national average participation rate measured in SNDA–III was 61.7 percent. The value of comparing changes in competitive food revenue to changes in NSLP revenue is limited to the extent that costs per dollar of gross revenue from the two sources differ. Although we do not have the data necessary to estimate profit margins on competitive foods, we expect that margins on NSLP meals and à la carte items, the most important subgroup of competitive foods, are similar.

We assume in our estimates that other school groups incur the same percentage change in competitive food revenue as SFAs. This assumption may not be realistic given the difference in the nature of the foods sold in occasional fundraisers, in vending machines, in snack bars, and in à la carte lines. However, given the importance of this revenue source for its sponsors, we expect that small or independent school groups will adapt in a manner that result in a revenue impact comparable to that experienced by the SFAs.

[51] This is in contrast to the possibility that all students reduce their purchases by the same percentage.

[52] This relationship assumes that (1) the increase in NSLP participation must come from non-participants who bought competitive foods as part of lunch, (2) that the decrease in competitive food purchases occurs as a reduction in the number of students purchasing competitive foods while students still purchasing competitive foods do not change their behavior, and (3) the proportion of students who switch from purchasing competitive foods as part of lunch to NSLP participation is the same as the additional proportion of students who participate in NSLP in schools where competitive foods are not available.

Scenario 1: High Student Acceptance of New Competitive Foods

For this scenario, we look to the experience of schools and school districts that have maintained or increased competitive food sales after introduction of healthier standards. With relatively modest efforts to engage students in developing standards and to promote healthier choices, these schools have demonstrated that student demand for healthier competitive foods can be maintained or increased.

Most competitive food revenue is generated by sales of à la carte foods. If competitive food revenue continues to be driven largely by à la carte sales, and the transition to healthier school meals (and, by extension, healthier à la carte items) is complete prior to the publication of competitive food standards, then the incremental effect of those standards on competitive food revenue in the short term could be relatively small.

Under this scenario, we assume a modest increase (five percent in SY 2015–2016 following no change in the first year of implementation) in competitive food revenue during the initial transition to healthier competitive foods. We choose five percent to match the minimum competitive food revenue increase recorded by three of ten schools in the California Healthy Eating Active Communities study (Woodward-Lopez, et al., 2010).

We then account for the costs incurred by schools that have already adopted competitive food standards. While we cannot precisely quantify these costs and revenue impacts, our review of the standards in place in the four largest States and the nation's largest school district provides a basis for a lower bound adjustment: we reduce all of our estimates by 20 percent. After the 20 percent adjustment, we estimate an increase in competitive food revenues of four percent ($\Delta CF = 4.0$).

Case studies confirm the general NSLP participation effect described in SNDA–III, suggesting that an increase in competitive food purchases after implementation of the proposed rule may come at the expense of NSLP participation. Because this scenario assumes a small increase in competitive food revenues, we estimate that SFAs will experience a slight (0.3 percent) decrease in school meal participation ($\Delta L = -0.3$).

We attribute 36 percent of the 0.3 percent change in the lunch participation to students who are eligible for free and reduced-price meals, and the other 64 percent to students who pay full price,[53] based on unpublished results showing that 64 percent of competitive food purchases were made by students not eligible for free or reduced-price meals.[54] Our analysis also utilizes the proportions of free, reduced-price, and paid lunches served projected by USDA for the FY 2013 President's Budget. For FY 2011, the observed proportions were 58, 8, and 33 percent for free, reduced price, and paid meals.

Using our estimate of a 0.3 percent decrease in NSLP participation, we estimate effects on school meal participation, SFA revenues from reimbursable meals, and Federal reimbursement costs.[55] Federal reimbursements are necessarily lower than SFA revenues for the same meals since the SFA revenue includes student payments for meals served at reduced or full price. Our estimated reduction in Federal costs is the product of the estimated decrease in NSLP meals multiplied by projections of the value of the reimbursements for free, reduced price, and paid meals.[56] The net impact in schools whose experiences align with this estimate is an overall school food revenue increase of roughly 0.4 percent.

Scenario 2: Lower Competitive Food Sales With Fully Offsetting Increases in School Meal Participation

Evidence of the effects of nutrition standards on revenues from competitive foods and beverages for this estimate is drawn from a case study of Texas schools (Cullen and Watson, 2009).[57] USDA's analysis of the Texas data concluded that overall competitive food purchases declined by six percent. Assuming each purchase contributes roughly equivalently to revenues, this would suggest a six percent decline in revenue from competitive food sales. To adjust for States and school districts that have already adopted competitive food standards, we assume that 20 percent of the revenue impact has already been realized nationwide. That reduces the estimated six percent competitive food revenue loss to 4.8 percent ($\Delta CF = -4.8$)

In this scenario, we model the effects of moderately high acceptance of competitive foods that meet proposed rule standards. As students reduce their competitive food consumption in search of alternatives, many turn to reimbursable meals. After implementation of changes to competitive food and school meal standards, many of the items offered à la carte (the largest component of SFA competitive food sales) will be identical to components offered in reimbursable meals. In this scenario, those most likely to turn away from competitive foods are also those who recognize that they may be able to get the same foods at lower price in an NSLP meal ($\Delta L = 2.0$). The net impact in schools whose experiences align with this scenario is a small decrease in overall school food revenue of roughly -0.03 percent.

It is possible that students' economic circumstances will play a role in their decision to replace competitive foods with reimbursable meals. Once reimbursable meals and competitive foods are subject to comparably healthy standards, and the difference between competitive foods and a reimbursable meal is reduced largely to price, increased participation in the reimbursable meals program may be particularly attractive to students who qualify for free or reduced-price benefits.

Scenario 3: Lower Competitive Food Sales With Partially Offsetting Increases in School Meal Participation

We illustrated above what could happen if competitive food revenue falls by 4.8 percent ($\Delta CF = -4.8$) and schools experience a fully offsetting increase in school lunch participation. It is possible, however, that fewer students will opt for school meals, preferring to bring lunch from home or perhaps purchase foods from outside vendors. For Scenario 3 we maintain the reduction in competitive food revenue but suggest a lower increase in NSLP participation. If NSLP participation increases 0.36 percent ($\Delta L = 0.36$), the net impact in schools whose experiences align with this estimate is a small decrease in overall school food revenue of roughly -0.7 percent.

C. Impacts on Participating Children and Families

Beyond revenue impacts to SFAs and other school groups, changes in food purchasing choices caused by the proposed rule will also have an economic effect on children and their families. The projected decreases in competitive food revenues represent reductions in spending by school children and their families on school-provided competitive foods. We do not have sufficient information to estimate increases or decreases in overall spending by students who find alternatives to school-provided competitive foods. Some students will spend less overall by replacing competitive foods consumption with free or reduced price school meals. A decrease in competitive food sales may also increase foods brought from home and/or foods purchased outside of schools. These imply revenue increases for food industries that sell foods brought from home and purchased outside the school setting.

The rule will not impact all students in the same way. For example, price and availability of competitive foods may differ by region of the country, constraining choices for some but not all students. For some students, choices will be limited by their incomes. For other students, alternatives to competitive foods will be limited by school policy; students at schools with closed campuses will have fewer options, but may benefit by choosing healthier foods as a result.

D. Administrative Costs

Under the proposed rule, local educational agencies (LEAs) and SFAs will be required to maintain records such as receipts, nutrition labels, and/or product specifications for food items that will be available to students on the school campus during the school day. The purpose of this documentation is to ensure that those foods comply with the competitive

[53] Paid, reduced price, and free NSLP meals each have some level of government subsidy, therefore even lunches that are ''full price'' are subsidized.

[54] Unpublished ERS analysis of SNDA–III data.

[55] Our baseline number of NSLP meals, like our baseline NSLP revenue, begins with FNS program projections prepared for the 2013 President's Budget. These are adjusted for the changes in lunches served as a result of the recently published rule to implement Sections 205 and 206 of the HHFKA. See rule and RIA in **Federal Register**, Vol. 76, No. 117, pp. 35301–35318.

[56] FNS projections of Federal reimbursements for free, reduced price, and paid lunches are those used to prepare the FY 2013 President's Budget, adjusted for changes for Sections 205 and 206 of HHFKA.

[57] The analysis that follows reflects the work of both the USDA's ERS and the FNS.

food standards. Thus, there will be recordkeeping costs associated with the proposed rule and these costs will occur at the State agency level, the SFA and LEA level, and at the school level. The estimated additional annual burden for recordkeeping under the proposed rule is 926,935 hours, divided among the State agencies (1,040 hours), LEAs and SFAs (417,160 hours), and schools (508,735) hours. Our estimate uses data from the Bureau of Labor Statistics on wages and salaries for State and local government employees and assumes no growth in burden hours over time. Wages are inflated using estimates from the 2013 President's Budget.[58] Note that there are no new reporting requirements in the proposed rule.

TABLE 3—ESTIMATE OF ADMINISTRATIVE COSTS FOR RECORDKEEPING FOR PROPOSED RULE

Recordkeeping	Fiscal year (millions)					
	2014	2015	2016	2017	2018	Total
State Agencies	$0.03	$0.03	$0.03	$0.03	$0.03	$0.14
SFAs and LEAs	10.8	11.1	11.5	11.9	12.2	57.4
Schools	13.1	13.5	14.0	14.5	14.9	70.0
Total	23.9	24.7	25.5	26.3	27.2	127.6

It is also possible that some schools and LEAs may have additional costs due to the proposed rule. For example, some schools may require new equipment such as vending machines to accommodate new products and package sizes. Additionally, schools and/or LEAs may have contracts with vendors that will require modification which could result in some additional labor cost. Those costs are not estimated here because we lack sufficient information on how many schools or LEAs could be affected and how those costs might be distributed among affected locations.

E. Industry Effects

Although they are not directly regulated by the proposed rule, food manufacturers and distributors will face changes in demand by schools and SFAs in response to the rule.

Manufacturers will face reduced school demand for some products and increased demand for others. Some food manufacturers may not have existing product lines that meet the proposed rule's requirements and may lose market share to other manufacturers. The impact of tightening the nutritional standards for food and beverages sold at public schools in the United States on food vendors is difficult to know ex-ante. It is likely that the elasticity of demand for food at schools is quite steep, implying that absent available alternatives, most consumption behavior will change aggregate sales by a small amount.

U.S. SFAs that participate in the NSLP purchased roughly $8.5 billion in food in SY 2009–2010, including the value of USDA foods.[59] That represents only about 1.3 percent of the $644 billion worth of shipments from U.S. food manufacturers in 2010.[60] FNS estimates that SFA revenue from competitive food equals about 20 percent of overall SFA revenue (see Table 1). If we assume that the ratio of food cost to revenue is consistent between competitive foods and other school foods, then SFA purchases of competitive foods totaled about $1.7 billion in SY 2009–2010. That represents only about 0.3 percent of the $644 billion worth of shipments from U.S. food manufacturers in 2010.

According to the 2007 Economic Census, about 23.4 percent of food manufacturing sales are by firms with 100 or fewer employees.[61] If we assume that competitive food sales are distributed to firms in proportion to their share of overall sales, we can estimate that in 2010 figures, about $400 million of competitive food sales is carried out by these small businesses, out of over $150 billion in total sales by these firms.

Implementing nutrition standards for competitive foods will result in a more nutritious, and potentially more expensive, mix of foods offered. If we assume that the cost of these foods is, on average, seven percent higher under the new standards—comparable to the estimated cost increase for school meals under updated nutrition standards—and that this increase will reduce demand for these foods comparably to school meals,[62] we would expect to see a two percent reduction in overall sales of competitive foods—about $34 million of the $1.7 billion in sales estimated for SY 2009–2010, with about $8 million of these losses experienced by small business.

While data is not available to estimate the possible distributional effects across the food industry overall, research indicates that some of the marketplace changes that would be required under the proposed standards are already taking place. Wescott et al. (2012), for example, found that between 2004 and 2009 the beverage industry reduced the number of calories shipped to schools by 90 percent, with a total volume reduction in full-calorie soft drinks of over 95 percent. Therefore, at least with respect to these products, many of the changes required by the proposed rule have already taken place under existing self-regulation and State and local standards, reducing the net impact of Federal standards relative to current conditions.

Local vending machine operators may also face some changes to their current business model. Although the effect of the proposed rule on individual operators will vary, available industry and school data suggest that the effect on this industry group as a whole will be small. Vending machine sales made up a small percentage of total competitive food revenue in SY 2004–2005. We estimate that à la carte sales accounted for 93 percent of total competitive food revenue. The remaining seven percent is generated by a variety of alternate sources. Although vending machines are the most common of these alternate sources of competitive food revenue (they were found in 52 percent of schools in SY 2004–2005 (Gordon, et al., 2007, vol. 1, pp. 96–100)) they are not the only alternate source. About 26 percent of schools offered competitive food in school stores, snack bars, food carts, and occasional fundraisers (Gordon, et al., 2007, vol. 1, p. 101).

Vending and manual foodservice operators served 19,000 primary and secondary schools in 2008, which was down about 14 percent from 2006 (VendingTimes.com, p. 3).[63] Primary and secondary schools accounted for just 2.2 percent ($1 billion out of $45.6 billion) of total vending machine sales in 2008 (VendingTimes.com, p. 3).

These data suggest that the impact of the proposed rule on the vending machine industry as a whole will be limited. Just a small share of vending industry revenue is generated in primary and secondary schools. And, importantly, some of that revenue is generated from sales of foods that are already compliant with the proposed rule standards, such as 100 percent juice and bottled water. Other products found in school vending machines in SY 2004–2005 were also likely

[58] We use wages and salaries for administrative employment in the state and local government sector from the Bureau of Labor Statistics' ''Employer Cost for Employee Compensation'' database (*http://www.bls.gov/data/home.htm*). For FY 2011, wages and salaries for these positions averaged $23.52 per hour. We inflate these through FY 2016 with projected growth in the State and Local Expenditure Index prepared by OMB for use in the FY 2013 President's Budget.

[59] USDA School Food Purchase Study III, 2012.

[60] Bureau of Economic Analysis, Gross Domestic Product by Industry, data for NAICS 311 and 312, excluding animal foods, tobacco and alcoholic beverages (*http://bea.gov/industry/xls/GDPbyInd_SHIP_NAICS_1998-2011.xls*)

[61] Bureau of the Census, 2007 Economic Census (*http://www.census.gov/econ/census07*)/.

[62] See Gleason, ''Participation in the National School Lunch Program and the School Breakfast Program,'' *Am J Clin Nutr* 61: 213S–220S.

[63] This figure is much smaller than the 52 percent of schools figure from SNDA–III. The vending industry data was gathered through a survey of vending machine operators, providers of coin-operated entertainment services, coffee-break service providers, and related industry subgroups.

compliant or near-compliant with the proposed rule.[64]

Both industry and Census Bureau data indicate that most vending machine operations are small businesses. The majority of vending machine operators that operated for the entire year in 2007 (76 percent) employed fewer than ten individuals according to the U.S. Economic Census.[65] About 37 percent of operators generated less than $250,000 in receipts, although those operators accounted for less than three percent of total revenue from this industry group.[66] Some small vendors may be challenged by the changes contained in the proposed rule. Whether small or large, many vending machine operators will need to modify their product lines to meet the requirements of the rule.

Limited data from California suggests that the transition to healthier competitive foods can be managed, that healthier foods can be marketed successfully in schools, and that competitive food sales outside of the à la carte line need not decline. In the first year healthier competitive food policies under California Senate Bill 19 (2001), seven of ten pilot sites that were able to report such data saw per capita decreases in non-foodservice competitive food sales (Center for Weight and Health, UC Berkeley, 2005, p. 12). However, vending machine and/or school store revenue increased in two other sites (both high schools) which led researchers to conclude that ''SB 19 compliant foods and beverages can be marketed successfully at the high school level'' (Center for Weight and Health, UC Berkeley, 2005, p. 12).

F. Distributional Effects

1. Revenues and Grade Level

Competitive food purchases and revenues are not equally distributed across schools. Elementary schools derive much less revenue from competitive foods than do secondary schools. They are typically smaller, much less likely to have vending machines, and usually serve a smaller assortment of à la carte items. According to SNDA–III, high schools obtain almost three times as much revenue from competitive foods as do elementary schools; therefore, changes in competitive food standards will have a greater impact at the middle- and high-school levels than they will in elementary schools.

2. Low-Income Students

Differences in competitive food revenues by free and reduced-price meal participation, one indicator of whether schools serve primarily lower-income students, are even more dramatic. According to SNDA–III, schools serving at least one-third of their meals at full price to higher income students obtain more than seven times as much revenue from competitive food sales as schools serving a larger percentage of free and reduced-price (and hence lower-income) students.[67] However as noted previously, revenues may drop more in terms of percentages at lower-income schools if low-income students are more price-sensitive than high-income students.[68] This difference is mirrored in the behavior of low income students. About two-thirds (64 percent) of competitive foods and beverages are selected by students who are not receiving free or reduced price meals.

Given these purchasing patterns, revenue losses would be substantial if students who previously bought competitive foods and beverages not allowed under the Federal standards simply stopped buying any foods. The revenue losses would be concentrated in secondary schools and schools serving higher proportions of non-poor students, i.e., students not eligible for free or reduced-price meals. However, case studies based on experience with established State- or district-level nutrition standards indicate that many students will substitute other competitive food and beverage purchases, or switch to purchasing USDA school meals. This would likely result in reducing revenue losses substantially. In predominantly low income schools, students may be even more inclined to turn to reimbursable meals if not satisfied with competitive food options. For those students, a free or reduced price meal may become the most attractive option.

Finally, there is some suggestion that access to healthy foods in schools varies by the socio-economic standing of the school and its neighborhood (Tipler, 2010). Improved nutrition standards for competitive foods could lessen the nutrition gap among schools.

G. Benefits

The proposed rule is intended to help ensure that *all* foods sold at school—whether provided as part of a school meal or sold in competition with such meals—are aligned with the latest and best dietary recommendations. They will work in concert with recent improvements in school meals to support and promote diets that contribute to students' long-term health and well-being. And they will support efforts of parents to promote healthy choices for children, at home and at school.

A growing body of evidence tells us that giving school children healthful food options will help them make healthier choices during the school day. In 2012, the Pew Health Group and the Robert Wood Johnson Foundation conducted an extensive Health Impact Assessment to evaluate potential benefits that could result from national standards for competitive foods sold in schools during the school day. They concluded that:

- A national competitive foods policy would increase student exposure to healthier foods and decrease exposure to less healthy foods; and
- Increased access to a mix of healthier food options is likely to change the mix of foods that students purchase and consume at school, for the better.

These kinds of changes in food exposure and consumption at school are important influences on the overall quality of children's diets. While nutrition standards for foods sold at school may not on their own be a determining factor in children's overall diets, they are a critical strategy to provide children with healthy food options throughout the entire school day, effectively holding competitive foods to the same standards as the rest of the foods sold at school during the school day. This, in turn helps to ensure that the school nutrition environment does all that it can to promote healthy choices, and help to prevent diet-related health problems. Ancillary benefits could derive from the fact that improving the nutritional value of competitive foods may reinforce school-based nutrition education and promotion efforts and contribute significantly to the overall effectiveness of the school nutrition environment in promoting healthful food and physical activity choices.

The link between poor diets and health problems such as childhood obesity are a matter of particular policy concern given their significant social and economic costs. Obesity has become a major public health concern in the U.S., second only to physical activity among the top 10 leading health indicators in the United States Healthy People 2020 goals.[69] According to data from the National Health and Nutrition Examination Survey 2007–2008, 34 percent of the U.S. adult population is obese and an additional 34 percent are overweight (Ogden and Carroll, 2010).

The trend towards obesity is also evident among children; 33 percent of U.S. children and adolescents are now considered overweight or obese (Beydoun and Wang, 2011), with current childhood obesity rates four times higher in children ages 6 to 11 than they were in the early 1960s (19 vs. 4 percent), and three times higher (17 vs. 5 percent) for adolescents ages 12 to 19 (IOM, 2007b, p. 24). These increases are shared across all socio-economic classes, regions of the country, and have affected all major racial and ethnic groups (Olshansky, et al., 2005).

Excess body weight has long been demonstrated to have health, social, psychological, and economic consequences for affected adults (Guthrie, Newman, and Ralston, 2009; Wang, et al., 2008). Recent research has also demonstrated that excess body weight has negative impacts for obese

[64] The SNDA–III data do not allow us to identify which other products in school vending machines are compliant with the proposed rule standards. Nor does the data allow us to estimate revenue from vending machine sales of compliant products. Nevertheless, the list of foods found in school vending machines includes several categories of products, in addition to water and 100 percent juice, that are likely compliant with the proposed rule, or include specific products that are compliant. These include milk, other lowfat dairy products, certain low calorie beverages, snacks such as pretzels and reduced-fat chips, and even fruits and vegetables. See Gordon, et al., 2007, pp. 104–105.

[65] Data for NAICS code 454210, ''vending machine operators.'' U.S. Census Bureau, *http://www.census.gov/econ/industry/ec07/a454210.htm* (accessed 11/13/2011).

[66] Ibid. Note that these statistics are for all vending machine operators in NAICS code 4545210, not just those that serve the school market. We do not know whether the concentration of small vending machine operators that serve the school market differs from the concentration of small operators in the industry as a whole.

[67] Unpublished ERS analysis of SNDA–III data.

[68] Woodward-Lopez, et al., 2010.

[69] ''Food Labeling: Calorie Labeling of Articles of Food in Vending Machines.'' NPRM. 2011.

and overweight children. Research focused specifically on the effects of obesity in children indicates that obese children feel they are less capable, both socially and athletically, less attractive, and less worthwhile than their non-obese counterparts (Riazi, et al., 2010).

Further, there are direct economic costs due to childhood obesity; $237.6 million (in 2005 dollars) in inpatient costs (Trasande, et al., 2009) [70] and annual prescription drug, emergency room, and outpatient costs of $14.1 billion (Cawley, 2004).

Childhood obesity has also been linked to cardiovascular disease in children as well as in adults. Freeman, Dietz, Srinivasan, and Berenson (1999) found that ''compared with other children, overweight children were 9.7 times as likely to have 2 [cardiovascular] risk factors and 43.5 times as likely to have 3 risk factors'' (p. 1179) and concluded that ''[b]ecause overweight is associated with various risk factors even among young children, it is possible that the successful prevention and treatment of obesity in childhood could reduce the adult incidence of cardiovascular disease'' (p. 1175).

It is known that overweight children have a 70 percent chance of being obese or overweight as adults. However, the actual causes of obesity have proven elusive (ASPE, no date). While the relationship between obesity and poor dietary choices cannot be explained by any one cause, there is general agreement that reducing total calorie intake is helpful in preventing or delaying the onset of excess weight gain.

There is some recent evidence that competitive food standards can improve children's dietary quality:

- Taber, Chriqui, and Chaloupka (2012) compared calorie and nutrient intakes for California high school students—with competitive food standards in place—to calorie and nutrient intakes for high school students in 14 States with no competitive food standards. They concluded that California high school students consumed fewer calories, less fat, and less sugar at school than students in other States. Their analysis ''suggested that California students did not compensate for consuming less within school by consuming more elsewhere'' (p. 455). The consumption of fewer calories in school ''suggests that competitive food standards may be a method of reducing adolescent weight gain'' (p. 456).
- A study of competitive food policies in Connecticut concluded that ''removing low nutrition items from schools decreased students' consumption with no compensatory increase at home'' (Schwartz, Novak, and Fiore, 2009, p. 999).
- Similarly, researchers for Healthy Eating Research and Bridging the Gap found that ''[t]he best evidence available indicates that policies on snack foods and beverages sold in school impact children's diets and their risk for obesity. Strong policies that prohibit or restrict the sale of unhealthy competitive foods and drinks in schools are associated with lower proportions of overweight or obese students, or lower rates of increase in student BMI'' (Healthy Eating Research, 2012, p. 3).

Pew Health Group and Robert Wood Johnson Foundation researchers noted that the prevalence of children who are overweight or obese has more than tripled in the past three decades, which is of particular concern because of the health problems associated with obesity. In particular, researchers found an increasing number of children are being diagnosed with type 2 diabetes, high cholesterol, and high blood pressure. These researchers further observed that children with low socioeconomic status and black and Hispanic children are at a higher risk of experiencing one or more of these illnesses (pp. 39–40, 56).

Their analysis also noted that:

[T]here is a strong data link between diet and the risk for these chronic diseases. Given the relationship between childhood obesity, calorie consumption, and the development of chronic disease risk factors at a young age, this report proposes that a national [competitive food] policy could alter childhood and future chronic disease risk factors by reducing access to energy-dense snack foods in schools.

To the extent that the national policy results in increases in students' total dietary intake of healthy foods and reductions in the intake of low-nutrient, energy-dense snack foods, it is likely to have a beneficial effect on the risk of these diseases. However, the magnitude of this effect would be proportional to the degree of change in students' total dietary intake, and this factor is uncertain (p. 68).

In summary, the most current, comprehensive, and systematic review of existing scientific research concluded that competitive foods standards can have a positive impact on reducing the risk for obesity-related chronic diseases.

Because the factors that contribute both to overall food consumption and to obesity are so complex, it is not possible to define a level of disease or cost reduction that is attributable to the changes in competitive foods expected to result from implementation of the rule. USDA is unaware of any comprehensive data allowing accurate predictions of the effect of the proposed requirements on consumer choice, especially among children. But to illustrate the magnitude of the potential benefits of a reduction in childhood obesity, based on $237.6 million in inpatient costs and $14.1 billion in outpatient costs, a one percent reduction in childhood obesity implies a $143 million reduction in health care costs.

Some researchers have suggested possible negative consequences of regulating nutrition content in competitive foods. They argue that not allowing access to low nutrient, high calorie snack foods in schools may result in overconsumption of those same foods outside the school setting (although as noted earlier, the Taber et al. study concluded overcompensation was not evident among the California high school students in their sample). Some groups have expressed concerns that the focus on competitive foods is less on nutrition than obesity, thus regulating competitive foods may contribute to bodyweight and/or appearance issues and result in increasing body insecurity feelings among children. The focus on obesity may also increase the stigmatization of children who are perceived as being obese.

H. Limitations and Uncertainties

We conducted this analysis using available data; due to the limitations of these data, there are some important qualifications to our analysis that should be noted. We discuss a few of these below.

1. Limitations in Available Research

Available research generally supports the notion that school food revenues will not necessarily be adversely affected by the implementation of healthier competitive food standards. Some schools or school districts, however, have seen revenue losses. Cullen and Watson (2009, p. 709) note that smaller districts might ''have more barriers associated with the bidding and food contract process and availability of alternative products'' relative to large districts. In addition, a five-month pilot program in North Carolina elementary schools saw decreases in competitive food sales with no offsetting increase in school meal participation. The published summaries of the pilot outcomes attribute all of the loss to reduced competitive food revenue and increases in the cost to schools of acquiring foods (NC GA 2011). North Carolina's State Superintendent commented on the lack of available foods that met the pilot standards and although she stated that increases in the availability of appropriate replacements would likely improve the economic impact of the healthier food standards, she still had concerns that healthier products may never generate the revenue necessary to meet North Carolina school needs (NC GA 2011, p. 2 Atkinson letter).

2. Prices of Competitive Foods

We do not have actual prices paid for specific competitive food and beverage items. While we assume that competitive items meeting and not meeting the proposed rule standards contribute equally to revenues, this is uncertain. It is likely that reformulated versions of existing competitive foods will cost at least as much as foods currently available, if for no other reason than the new items do not have the same market share. However, to meet calorie or fat standards, manufacturers may simply reduce package sizes, e.g., replacing 16 ounce 100 percent juice drinks with four or eight ounce bottles. In those cases, there is little reason to expect higher prices. Additionally, not all compliant foods will be close substitutes for existing foods, e.g., fruit drinks that are not 100 percent fruit juice may be replaced by bottled water at a similar or lower cost.

3. State and Local Support of Reimbursable Meals

Information on State and local payments in support of USDA school meals is not available. Some States and localities make payments that are tied to USDA school meal participation. If combined Federal, State, and local payments are greater (or less) than the

[70] Trasande, et al., 2009 report that between 1999 and 2005, hospitalizations related to obesity increased 8.8 percent among children ages 2 to 5, 10.4 percent among children 6 to 11, and 11.4 percent among children ages 12 to 19 after controlling for other factors.

costs of producing meals, SFAs would likely make lunch pricing decisions with a view toward optimizing their levels of Federal, State, and local subsidies.

4. Student Response to New Standards

Only a few limited case studies assess possible behavior change that may occur in response to the proposed rule. Even these limited studies are based on standards that are not exactly the same as the proposed rule. The local conditions in which they take place may not match national conditions. Implementation of State standards may have been accompanied by other factors, such as nutrition education or promotion of school meals, which may have influenced outcomes. While we believe that the evidence we examined is generally consistent with the suggestion that new standards will be associated with purchases of healthier competitive foods and increased school meal participation, data limitations create considerable uncertainty about the size of these changes. We also lack information on changes in purchasing behavior over time. As students adjust to the new range of competitive options, their purchasing behavior could adapt, altering revenue patterns.

5. Industry Response

This analysis assumes that food manufacturers and vendors, SFAs, and other school groups that sell competitive foods and beverages will adapt their behaviors in response to the proposed rule. Studies of State and local changes in competitive food and beverage policies indicate that these behavioral changes will occur (Cullen and Watson, 2009; Wharton, Long, and Schwartz, 2008; Woodward-Lopez, et al., 2010; USDA 2005). We draw on this literature to estimate the possible effects of behavioral changes on competitive food and beverage revenues.

This literature indicates that to a large extent, lost revenues from products that can no longer be sold in schools because of the proposed rule may be offset by increased purchases of products that are already widely available and purchased as competitive items (for example, bottled water) or by purchases of newly available, healthier products. In some cases changes are relatively simple. For example juices currently sold in 12-oz containers could be sold in 8-oz or 4-oz containers, as appropriate for grade level. In other cases, reformulations of existing products are already underway. Actions by State agencies and voluntary groups such as Alliance for a Healthier Generation have already encouraged food manufacturers to develop new products for competitive food sales: 4-oz fruit bowls; nonfat, no-sugar added frozen yogurt; 4-oz frozen fruit bars; and reduced-fat and sodium pizza with whole grain crust (Alliance for a Healthier Generation, 2010). Food service staff in California, however, also reported that more products are needed and that the costs of such products are frequently higher than those they replace (Woodward-Lopez, et al., 2005b).

Establishment of Federal standards is likely to spur further product development and increased sales volume that may help to bring prices in line with those of less-nutritious competitive items. Because State and local experience to date has preceded the establishment of Federal standards, their results may overstate the challenges that schools will face in implementing the proposed rule. The pressures on school revenue from high costs and limited availability could ease in the period between publication of proposed rule standards and the effective date of a final rule.

6. SFA and School Compliance

Early studies on competitive food revenues indicate that not all schools have complied with existing State competitive food standards.[71] This may be due, in part, to a lack of approved product choices, especially for early implementers. Compliance may be less of a challenge with national standards, especially as industry and students continue to adapt to State standards already in place. But, to the extent that schools fail to implement or fully enforce certain provisions of the proposed rule, the revenue impact of the rule will be lower. Each of our estimates assumes full compliance with the proposed rule.

7. School Participation Federal Meal Programs

It is possible that some schools could choose to leave NSLP and SBP to avoid the new competitive food standards. Although some schools may realize significant losses in revenue from competitive foods, especially in the short term, we believe it is unlikely that many, if any, will choose to do so. On average, SFAs receive just 16 percent of their total revenue from competitive foods; 84 percent of revenue is derived from Federal reimbursements for NSLP and SBP meals, student payments, and State and local contributions tied to those meals (USDA, 2008).

8. Food and Labor Costs

This analysis focuses on revenues in SFAs and other school groups. It does not address food and labor costs directly because few of the research reports and case studies report detailed cost information. One study (Treviño et al., 2012) that did report expenses and labor costs in addition to revenues found no statistically significant difference between intervention and control schools after the intervention schools implemented stronger competitive food standards. Although the differences were not statistically different, intervention schools were found to have higher excess revenue over expenses than the control schools ($3.5 million versus $2.4 million) (pg. 421).

Although we do not address costs directly, we expect that cost will have a limited effect on the net revenue of SFAs and other school groups. SFA competitive food revenue is derived primarily from à la carte sales. Under the proposed rule, à la carte items that are available as part of a reimbursable meal are deemed to meet the new standards and those items will be subject to new school meal standards under regulations that will take effect prior to this competitive foods rule.[72] To the extent that schools' à la carte lines are stocked with school meal entrées, side dishes, and beverages that are also available in reimbursable meals, much of the cost of providing healthier à la carte items will have been incurred before competitive food standards take effect.

This does not apply, of course, to à la carte items that are not components of a reimbursable meal or to items sold in vending machines or through other outlets; schools may incur higher costs to replace those items with items that meet this rule's standards. However, even for those foods, industry and schools will have had some time after implementation of new school meals standards to prepare. Some of the fixed costs of product development, contracting with new suppliers, developing recipes, and training kitchen staff will have already been incurred by industry and schools as they implement Federal school meal standards, easing pressure, perhaps, on prices and the administrative costs of complying with this competitive foods rule.

IV. Alternatives

A. Full Implementation of IOM Recommendations

We first consider a rule that adopts all of the IOM standards without change. The standards in the proposed rule were guided in large part by the IOM standards, but were also informed by other considerations. Thus, for example, the proposed rule allows a broader array of products in high schools than are included in the IOM standards. In addition, some of the IOM standards are more restrictive than those contained in the proposed rule, and it is possible that fewer currently available food products meet the standards.

The overall revenue effect on SFAs that lose competitive food sales depends on the extent to which students replace consumption of competitive foods with increased participation in the NSLP, an unknown that may vary according to characteristics of the student population (such as percent of children eligible for free or reduced price meals) or school policy (allowing students to leave campus at lunch time). Strong growth in NSLP participation, reported by some schools, would fully offset the reduction in competitive food receipts. However, lesser growth in NSLP participation allows for the possibility of substantial overall revenue losses.

B. Less Comprehensive Standards

A second alternative considered would place fewer restrictions on the types of competitive foods and beverages available to students. Under this scenario, students would likely have a wider range of options and, potentially, the choices available to students would contain more of the foods that they are already familiar with. This alternative increases the likelihood that there will be no net loss in competitive food revenue.

[71] See, for example, SNDA–III, V. 1, 2007; Woodward-Lopez, et al., 2005b; Bullock, et al., 2010; Woodward-Lopez, et al., 2010.

[72] The proposed school meal standards rule was published in January, 2011. See **Federal Register** Vol. 76, No. 9, p. 2494.

Less comprehensive competitive food standards could also have implications for children's health. The competitive food standards are crafted specifically because of concern about children's health and especially childhood obesity. Thus adopting less comprehensive standards could reduce the positive impact of the proposed standards on children's health.

C. Exemption for Reimbursable Meal Entrées and Side Dishes

As noted previously, many of the food items sold à la carte are entrées or snacks that are also served as part of a reimbursable meal. The proposed rule provides three alternative standards for NSLP menu items sold à la carte. The first would allow NSLP entrées and snacks to be sold any time as an à la carte food as long as they meet the fat and sugar standards in the proposed rule. The other two alternatives have to do with the menu cycle; providing NSLP entrée and snack items to be sold (1) on the same day they were served as part of a reimbursable meal, or (2) within four days of being served as part of a reimbursable meal.

The primary benefit of an exemption that is limited to foods on the current day's menu is that those items could be offered à la carte no more often than they could be served in reimbursable meals without exceeding weekly NSLP or SBP restrictions on average calories, fat, or sodium. This more limited exemption would also encourage students to consume a greater variety of foods, even if they choose foods consistently from the à la carte line. However, an exemption that is limited to entrées and side dishes on the current day's menu could complicate meal planning and preparation by denying schools the ability to serve leftover items on the next school day.

The primary benefit of an exemption within four operating days of its offering in an NSLP or SBP menu is that it would ease school planning and increase efficiency by allowing the service of leftover items more flexibly. However, it could discourage variety in student consumption, and may tend to increase consumption of entrees higher than average in calories, fat, and sodium that in the school meals programs are balanced by other offerings during the week.

D. School-Sponsored Fundraisers

The proposed rule offers two alternatives on exempt fundraisers. The first alternative is to allow State agencies to set the frequency of exempt fund raisers and the second is similar; State agencies would still set the frequency of exempt fund raisers, but subject to USDA approval. The proposed rule complements the Federal nutrition standards for reimbursable meals that take effect at the start of SY 2012–2013. Together, these reforms are designed to create the all-venue, day-long healthy school food environment recommended by IOM.[73] The consistency of the message on healthy eating conveyed to students through these measures is diminished by frequent exemptions for fundraisers. If a consistent message is more effective in influencing eating habits than an inconsistent message, then frequent fundraiser exemptions may reduce long-term student adherence to a diet consistent with the Dietary Guidelines. It is also important to note that current practice in many schools is quite limited. More than half of all schools, and 39 percent of high schools, never sold sweet or salty snacks as fundraisers in SY 2004–2005.

The benefits of partial or full State discretion derive from State administrators' knowledge of what will prove most effective in their schools. State discretion may, for example, give rise to creative policies that encourage districts to move away from food-based fundraisers while allowing for a short transition period that recognizes individual districts' dependence on such revenue. Through this type of flexibility, it is possible that State discretion would ultimately result in fewer exempt fundraisers than would be the case under a uniform national standard.[74] However, the option that would give States full discretion over exempt fundraisers entails some small risk that one or more States or school districts (if States use their discretion to leave the decision to local districts) will adopt standards that impose little or no restriction on the frequency of exempt fundraisers. A policy that does not limit the frequency of exempt fundraisers risks undermining the goals of Federal competitive food and reimbursable meal regulations.

Providing States with partial discretion over the frequency of exempt fundraisers could also potentially result in a modest increase in administrative costs at both the State and Federal levels. That option will require the development of policies on the acceptability of State standards, and procedures to administer the application and approval process.

E. Total Sugar

The proposed rule's alternative sugar standards for competitive foods would limit total sugar content to either 35 percent of calories or 35 percent of weight. Both standards would place a meaningful check on the amount of sugar allowed in competitive foods while providing exceptions for certain fruit and vegetable snacks and yogurt.

The calorie-based standard would be more restrictive than the weight-based standard for sugar-sweetened foods with high moisture content, such as ice cream and other frozen desserts.[75] The proposed rule's calorie-based standard would not disallow those foods, but *for some individual products,* the calorie-based standard would require that they contain less sugar than the weight-based standard for an identically sized serving.[76]

For products with low moisture content the ratio of fat to sugar is more critical. Because a gram of fat has more than twice as many calories as a gram of sugar, snack products and desserts with a relatively high fat content (from nuts or chocolate, for example) may be disallowed under the proposed rule's weight-based sugar standard while meeting its calorie-based standard.[77]

F. Naturally Occurring Ingredients and Fortification

Competitive foods that do not satisfy one of the proposed rule's food group requirements may still be sold to students if they provide at least 10 percent of the daily value of a ''naturally occurring'' nutrient of concern: Calcium, potassium, vitamin D, or dietary fiber. Naturally occurring nutrients are those found in non-fortified foods. As an example, the preamble to the rule lists dry milk solids, cheese, or rhubarb as naturally occurring sources of calcium. Processed foods that use these naturally calcium-rich foods as ingredients can meet the proposed rule's calcium standard. Processed foods that are only able to reach the 10 percent daily value for calcium through fortification with a non-food source would not meet the standard. The primary alternative to this provision is to allow fortification with non-food ingredients.

The Department believes that recognizing only naturally occurring nutrient sources is more consistent with the recommendation of the Dietary Guidelines that ''nutrients should come primarily from foods'' (USDA–HHS 2010, p. 49). A rule that does not credit the contribution of non-food sources to meeting the rule's ten percent standard for DGA nutrients of concern is also better aligned with IOM recommendations. IOM cites ''[e]merging evidence for the health benefits of fruits, vegetables, and whole grains'' that ''reinforces the importance of improving the overall quality of food intake rather than nutrient-specific strategies such as fortification and supplementation'' (IOM, 2007a, p. 41).

Despite these benefits of a food-based approach, the Department recognizes that schools may be unable to distinguish products that satisfy the ''naturally occurring'' requirement from products that do not. At present, the contribution of food-based and non-food sources to the nutrient values on processed food nutrition labels are not shown separately. The practical effect of

[73] For schools to ''take full advantage of their unique position to model and reinforce healthy eating behaviors'' competitive food policies must ''consider foods and beverages offered in all venues and throughout the school day'' (IOM 2007a, pp. 25–26).

[74] States and local districts would be free, as well, to set policies that allowed fewer exempt fundraisers than a uniform national standard. However, only a policy of State discretion would allow relatively permissive local standards for a short transition period.

[75] Flavored milk is not subject to the proposed rule's total sugar standard.

[76] For example, 100 grams of ready-to-eat chocolate pudding (ID 19183 in the USDA National Nutrient Database for Standard Reference, release 24) contains 142 calories and 17.17 grams of total sugar. By weight, this product is 17.17 percent sugar, well under the proposed rule's 35 percent by weight standard. But 17.17 grams of sugar have 65 calories (at 3.8 calories per gram). That is 46 percent of the 142 total calories in this product, a figure that exceeds the proposed rule's 35 percent of calories standard (*http://ndb.nal.usda.gov/*).

[77] Certain varieties of trail mix, granola bars, and whole grain cookies sometimes fall into this group. Two examples from the USDA's National Nutrient Database for Standard Reference (release 24) are product IDs 25056 (chocolate coated granola bar) and 18533 (iced oatmeal cookie).

this limitation may be that schools will approve few competitive foods for sale on the basis of their calcium, potassium, vitamin D, or dietary fiber content alone. In an effort to exclude items that achieve targeted levels of these nutrients through non-food fortification, schools may disallow any item with non-food sources of these nutrients unless they also satisfy one of the proposed rule's food group requirements or other exemptions. A possible consequence is that the proposed rule will not contribute as effectively as intended to increasing student intake of these nutrients of concern.

It is unclear how cost might impact the mix of competitive foods offered for sale under these alternate provisions. If fortification with non-food sources of calcium, potassium, vitamin D, or dietary fiber is an inexpensive way for manufacturers to gain access to the school competitive food market, then a rule that allows non-food fortification may increase the variety and lower the cost of competitive food products available to students. At the same time, inexpensive fortified snacks and beverages may crowd out whole grains, fruits, vegetables, and dairy products.

G. Allowable Beverage Sizes in High Schools

The proposed rule would allow plain water, milk, nutritionally equivalent milk alternatives, and 100 percent fruit or vegetable juice to be sold to elementary, middle, and high school students outside of the meal service area. In addition to these, the proposed rule would allow schools to make certain calorie free and low calorie beverages available to high school students. (''Calorie free'' and ''low calorie'' are FDA standards.[78]) At the high school level, the proposed rule would limit all calorie free beverages to 20 fluid ounces and low calorie beverages to 12 fluid ounce containers. The proposed rule places no size limit on containers of plain water.

H. Low Calorie Beverages

The proposed rule's alternative calorie limit for beverages for high school students would permit up to either 40 calories per 8 fl oz serving (and 60 calories per 12 fl oz) or 50 calories per 8 fl oz serving (and 75 calories per 12 fl oz). The higher 50 calorie limit would permit the sale of some national brand sports drinks in their standard formulas.[79] The lower 40 calorie limit would only allow the sale of reduced-calorie versions of those drinks. The 50 calorie alternative would open the door to a class of competitive beverages with great market strength and consumer appeal. Such a change might generate significant revenue for schools and student groups.

IOM specifically excludes sports drinks from both its Tier 1 and Tier 2 lists of beverages. However, IOM does recognize their value for student athletes engaged in prolonged physical activity for ''facilitating hydration, providing energy, and replacing electrolytes'' (IOM, 2007a, p. 11). In these limited circumstances, IOM would endorse the decision of an athletic coach to make such drinks available.

I. Caffeinated Beverages

Consistent with IOM recommendations, the proposed rule requires that beverages served to elementary and middle school students be caffeine free or include only small amounts of naturally occurring caffeine. The proposed rule, however, does not restrict caffeinated products for high school students, which is a departure from the IOM guidelines. The Department invites comments on providing the exception for high school students.

V. Accounting Statement

As required by OMB Circular A–4, we have prepared an accounting statement showing the annualized estimates of benefits, costs and transfers associated with the provisions of this proposed rule.[80] As discussed throughout this impact analysis, available data do not allow us to develop point estimates of competitive food or reimbursable meal revenue effects with any certainty. For this reason, the only dollar figures presented in the accounting statement are those associated with Table 3's State agency, LEA, and school-level recordkeeping costs.

The accounting statement's cost figures are equal to the annualized, discounted sum of the estimated cost stream from Table 3:

	Fiscal year ($ millions)					
	2014	2015	2016	2017	2018	Total
Total projected nominal cost of final rule	$23.9	$24.7	$25.5	$26.3	$27.2	$127.6

Applying 7 and 3 percent discount rates to this nominal cost stream gives present values (in 2012 dollars):

	($ millions)					
	2014	2015	2016	2017	2018	Total
Total cost (present value, 7% discount rate)	$20.9	$20.1	$19.5	$18.8	$18.1	$97.4
Total cost (present value, 3% discount rate)	22.5	22.6	22.7	22.7	22.8	113.3

[78] ''Calorie free'' may be used on a label for foods with fewer than 5 calories per ''reference amount customarily consumed.'' Foods may be labeled ''low calorie'' if they contain no more than 40 calories per reference amount customarily consumed (21 CFR 101.60(b)).

[79] Nutrition labels on product Web sites for both Gatorade and Powerade show 50 calories per 8 fl oz serving.

[80] OMB Circular A–4 is available at *www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf.*

[81] The Excel formula for this is PMT(rate, # periods, PV, 0, 1).

The annualized values in FY 2012 dollars of these discounted cost streams are computed with the following formula, where PV is the discounted present value of the cost stream ($97.4 in the illustration), *i* is the discount rate (7 percent), and *n* is the number of years beyond FY 2012 (6).[81]

$$PV \div \left[\frac{1 - \frac{1}{(1+i)^{(n-1)}}}{i} + 1 \right]$$

$$97.4 \div \left[\frac{1 - \frac{1}{(1+0.07)^{(6-1)}}}{0.07} + 1 \right]$$

Benefits	Outcome scenario	Estimate	Year dollar	Discount rate	Period covered
Annualized Monetized ($millions/year)	n.a.	n.a.	n.a.	n.a.	FY 2014–2017.
Qualitative: The rule will ensure that all foods sold to children in school during the school day will meet macronutrient and food group standards that are consistent with a healthy diet and are based on current nutrition science. The proposed rule will encourage the consumption of foods such as whole grains, fruit, vegetables, and dairy products that are low in fat and added sugar. By allowing only the sale of competitive foods that comply with Dietary Guidelines recommendations, this proposed rule aims to promote healthy eating habits.					
Quantitative: SFA and State educational agency administrative expenses to comply with the rule's reporting and recordkeeping requirements.					
Annualized Monetized ($millions/year)	1–4	$19.1 $20.3	2012 2012	7% 3%	FY 2014–2017.
Qualitative: The changes in competitive foods offered by schools will likely result in changes in student expenditures on competitive foods (sold by SFAs and non-SFA school groups). It will also change the extent to which students purchase and consume reimbursable school meals, resulting in changes in amounts transferred from students to school food authorities, and from USDA to school food authorities, for reduced price and paid meals. We have modeled a number of potential scenarios based on available data to assess impacts of competitive food standards on overall school food revenue. While they vary widely, each scenario's estimated impact is relatively small (+0.4 percent to −0.7 percent). The data are insufficient to assess the frequency or probability of schools experiencing any specific level of impact.					

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FEDERAL REGISTER

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Part IV

The President

Federal Register
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Presidential Documents

Title 3—

The President

Presidential Determination No. 2013–04 of January 29, 2013

Unexpected Urgent Refugee and Migration Needs Relating to Syria

Memorandum for the Secretary of State

By the authority vested in me as President by the Constitution and the laws of the United States, including section 2(c)(1) of the Migration and Refugee Assistance Act of 1962 (the ''Act''), as amended (22 U.S.C. 2601(c)(1)), I hereby determine, pursuant to section 2(c)(1) of the Act, that it is important to the national interest to furnish assistance under the Act, in an amount not to exceed $15 million from the United States Emergency Refugee and Migration Assistance Fund, for the purpose of meeting unexpected urgent refugee and migration needs, including by contributions to international, governmental, and nongovernmental organizations and payment of administrative expenses of the Bureau of Population, Refugees, and Migration of the Department of State, resulting from the crisis in Syria.

You are authorized and directed to publish this memorandum in the *Federal Register*.

THE WHITE HOUSE,
Washington, January 29, 2013.

[FR Doc. 2013–03108
Filed 2–7–13; 11:15 am]
Billing code 4710–10

Presidential Documents

Memorandum of January 31, 2013

Delegation of Authority To Suspend the Provisions of Title III of the Cuban Liberty and Democratic Solidarity (LIBERTAD) Act of 1996

Memorandum for the Secretary of State

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3 of the United States Code, I hereby delegate to you the authority to suspend the provisions of title III of the Cuban Liberty and Democratic Solidarity (LIBERTAD) Act of 1996 (Public Law 104–114; 22 U.S.C. 6021–6091), as authorized by section 306(c)(2) of the Act.

You are authorized and directed to publish this memorandum in the *Federal Register*.

THE WHITE HOUSE,
Washington, January 31, 2013.

[FR Doc. 2013–03110
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